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No. 01-

IN THE
Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that the state-law damages claims at issue there were not preempted by the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act, 21 U.S.C. 360k(a). The Court did not, however, explicitly decide whether its no-preemption ruling applies where the medical device alleged to have caused the plaintiff's injury has been granted pre-market approval by the Food and Drug Administration ("FDA"). Since *Medtronic*, the lower federal courts and state courts of last resort have become deeply divided over that question. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). In addition, the United States has taken the position that pre-market approval does not trigger preemption. *See infra* at 20.

The question presented is:

> Did the court below err in holding that petitioners' state-law damages claims are expressly preempted by the MDA solely because the FDA had granted pre-market approval for the medical device alleged to have caused petitioners' injuries?

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Billye Jeanne Martin and Lirba Salazar respectfully request that the Court issue a writ of certiorari to review the Fifth Circuit's ruling that their state-law damages claims, seeking recovery for injuries caused by a medical device, are preempted by the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act.

OPINIONS BELOW

The opinion of the Fifth Circuit is reported at 254 F.3d 573, and is reproduced in the appendix to this petition at 1a. The United States District Court for the Southern District of Texas issued two relevant decisions in each of petitioners' cases, none of which are reported. The decisions in Ms. Martin's case are reproduced at 23a and 33a. The decisions in Ms. Salazar's case are reproduced at 36a and 46a.

JURISDICTION

The judgment of the Fifth Circuit was entered on June 18, 2001 (1a). This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. 360k provides in part:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for

human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in

which the requirements are not limited to devices....

STATEMENT OF THE CASE

Introduction

Petitioners Billye Jeanne Martin and Lirba Salazar were implanted with a pacemaker lead manufactured by respondent Medtronic, Inc. The lead is a wire that delivers an electrical impulse from a pacemaker's "pulse generator" to the patient's heart. Because of defects that ultimately led to withdrawal of the product from the market, their leads malfunctioned, causing them damages, including medical expenses, physical injuries, pain and suffering, and other losses. Both Ms. Martin and Ms. Salazar filed suit against respondent, and because their cases presented the identical legal question they were consolidated on appeal by the U.S. Court of Appeals for Fifth Circuit. This petition presents the question whether petitioners may seek recovery for their injuries under Texas law, or whether, as respondent maintains and the Fifth Circuit below held, the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act — enacted in 1976 to protect consumers from potentially dangerous medical devices — bar them from recovering their damages.

The Court should grant review for two related reasons. First, since the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the federal and state appellate courts have become deeply divided on the precise question presented here: whether state-law damages claims concerning medical devices that have been approved by the Food and Drug Administration ("FDA") under the MDA's pre-market approval ("PMA") process are preempted. In fact, three circuit courts have now reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached

exactly opposite results. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (applying *Lohr* and finding no preemption of state-law damages claims), *with* 1a (Fifth Circuit decision below, applying *Lohr* and finding preemption of all state-law damages claims) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (same), *pet. for cert. pending*, No. 00-1766 (filed May 24, 2001). *See also, e.g., Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (finding no preemption on same issue).

Second, the Court should grant review because a significant number of appellate courts have erroneously reaffirmed broad pre-*Lohr* interpretations of the MDA's preemption provision, 21 U.S.C. 360k(a). Like the decision below, these courts have mistakenly held that the FDA's approval of a PMA application constitutes a specific preemption-triggering federal "requirement" under section 360k(a) and have failed to follow *Lohr*'s holding that claims based on state-law duties of general applicability are not preempted. *See Lohr*, 470 U.S. at 501-02.

Part A below describes the structure of the MDA, and Part B discusses this Court's decision in *Medtronic v. Lohr, Inc.*, which interpreted the MDA's preemption provision and has spawned conflicting views in the state and federal appellate courts on the meaning of that provision. Part C explains the factual background and district court proceedings in this case. Finally, Part D describes the holding of the Fifth Circuit below.

A. The Medical Device Amendments.

The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process by which devices could reach the market. H.R. Rep. 853, 94th

Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. 360c *et seq.*). Every medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853, *supra* at 34; 21 U.S.C. 360c(a). Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). Thus, the FDA may subject them to "special controls," such as the agency's specific warning labels for tampons. *See* 21 C.F.R. 801.430(c), (d) & (e).

Finally, class III devices — such as the pacemaker leads at issue here and in *Lohr* — are those that, in general, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). This process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[1]

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[1]Certain class III devices, such as the one at issue in *Lohr*, can be marketed without going through the full PMA process. If the FDA finds that a Class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for

(continued...)

Three components of the regulatory structure are relevant to this petition. First, when it approves a manufacturer's PMA application, the FDA does not warrant that the device is free of defect in design, manufacture, or labeling. And, of critical importance here, the FDA does not, as part of the PMA process, require or specify the device's design, manufacturing process, or labeling, nor does it conduct testing or studies regarding the device. Rather, a device's design, manufacture, and labeling originate with the applicant (the device manufacturer), on whose data the FDA depends in acting on the PMA application. 21 C.F.R. 814.20, 814.44. As in this case, the FDA issues a form approval letter reminding the manufacturer of its obligations under federal regulations. There is nothing device-specific in the form approval letter.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, in addition to the tampon warning label mentioned above, the FDA has required that hearing aids bear certain labels and that tampon absorbency be tested in a specific manner. *See* 21 C.F.R. 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for pacemakers or their component parts, such as the pacemaker lead that caused petitioners' injuries.

Third, the MDA contains a preemption provision, 21 U.S.C. 360k(a), which preempts certain state-law "requirements" "with respect to a device" if they are "different

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[1](...continued)
approving such devices is sometimes referred to as the "510(k)" process after the section of the Food, Drug, and Cosmetic Act under which the device application is submitted. *See Lohr*, 518 U.S. at 478.

from, or in addition to" MDA "requirements." Under 21 U.S.C. 360k(b), the FDA has the authority to exempt from preemption certain state requirements that would otherwise be preempted. Thus, the FDA has issued regulations concerning the scope of MDA preemption, *see generally* 21 C.F.R. Part 808, which reflect section 360k(a)'s narrow reach. *See Lohr*, 470 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation"). For instance, the regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. 808.1(d). Likewise, to be preempted, state-law requirements also must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates ... to other products in addition to devices." *Id.* § 808.1(d)(1).

B. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510k "substantial equivalence" process. This Court held that none of Lohr's claims — based on defective design, defective manufacture, and failure to warn — was preempted by the MDA.

1. *The Majority Opinion.* Although there was a concurrence and a partial dissent in *Medtronic*, the majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 470 U.S. at 480; *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) Lohr's design-

defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations are not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that Lohr's damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found, the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the

majority held, the claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[2]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He therefore did not join the plurality opinion (*see supra* note 2), because he was not convinced that MDA preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to Lohr's claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 470 U.S. at 505-06 (citing, *e.g., Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.* at 506.

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[2]Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. *Id.* at 488-91 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of Lohr's claims was preempted. *Id.* at 502-03.

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. In her view, state-law damages claims can constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that Lohr's design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

C. Background Facts and District Court Proceedings.

As noted earlier, although this petition involves two separate lawsuits filed by two different individuals, both cases concern the same legal issue and involve the same medical device. The product that caused petitioners' injuries is Medtronic's 4004 pacemaker lead. 2a-3a. The FDA approved Medtronic's application in March 1990, as a supplement to a pre-market approval ("PMA") that had been granted to an earlier version of the device. *See* 25a.

After the product's approval, it was discovered that the 4004 ran a significant risk of failure caused by degradation of its polyurethane insulation. As a result, in October 1993, respondent issued a "Health Safety Alert" to the medical community and withdrew the remaining 4004 leads from the market. *See Kemp,* 231 F.3d at 219. Unfortunately, the 4004's withdrawal came too late for Ms. Martin and Ms. Salazar, who had already been implanted with the defective device. *See* Original Petition in *Martin*, ¶ IV; Complaint in *Salazar,* ¶ IV.

Ms. Salazar brought suit in August 1996, based on diversity of citizenship under 28 U.S.C. 1332, in the United States District Court for the Southern District of Texas. In the same month, Ms. Martin brought suit in state court in Nueces County, Texas, and respondent removed the case to the same federal court on diversity grounds under 28 U.S.C. 1441(a). Thereafter, although the two cases were not consolidated, the district court heard them together, and its orders regarding preemption in the two cases are nearly identical. The complaints in both cases allege claims based on negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act, Tex. Bus. & Com. Code 17.41 *et seq.* Original Petition in *Martin*, ¶¶ VIII-XII; Complaint in *Salazar*, ¶ V; *see* 3a. In particular, petitioners' DPTA claims alleged breaches of express and implied warranties, failure to disclose known defects, misrepresentation, and unconscionability. *See* Tex. Bus. & Com. Code 17.46(b)(2), (5), and (7), 17.50 (a)(2) and (3). Petitioners' claims focused on defects in the design and manufacture of the pacemaker lead and the failure of respondent to warn about the product's hazards. 3a.

The district court held that all of petitioners' claims are preempted by the MDA, and granted summary judgment to respondent. The district court noted that, prior to this Court's decision in *Lohr*, the Fifth Circuit had held that design-defect and failure-to-warn claims with respect to a device that had undergone FDA pre-market approval are preempted by the MDA. *See* 28a, 41a (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993)). The court stated that *Lohr*'s no-preemption holding was "distinguishable" from *Stamps* because the device in *Lohr* had not gone through the PMA process. The court thus ruled that all of petitioners' claims challenging the design and manufacture of the 4004 lead, as well as all claims based on failure to warn, are preempted (31a, 43a-44a), but held

that any claim that respondent did not use the PMA processes actually approved by the FDA would not be preempted and granted petitioners time to develop such a claim. Petitioners did not pursue that claim and the court thereafter granted respondent final summary judgment on preemption grounds. 33a-35a, 46a-48a.

D. The Fifth Circuit's Decision.

The Fifth Circuit affirmed the grant of summary judgment to respondent on all of petitioners' state-law damages claims. The court began by noting that under its pre-*Lohr* decision in *Stamps v. Collagen Corp.*, 984 F.2d 1416, petitioners' claims would be preempted. 2a. Calling its earlier ruling "central to our resolution of this appeal," 5a, the court stated that "*Stamps* should apply to this case unless 'an intervening Supreme Court case explicitly or implicitly overrule[es] that prior precedent.' ... Thus, the first, and ultimately only, question we face is the degree to which *Stamps* retains precedential value after the Supreme Court's decision in *Lohr*." 6a (quoted case citation omitted).

The court stressed that "the Supreme Court decision must be more than merely illuminating with respect to the case before us, because a panel of this court can only overrule a prior panel decision if 'such overruling is unequivocally directly by controlling Supreme Court precedent.'" 6a (quoted case citation omitted). "[O]ur question," the court later noted, "is not whether the panel in *Stamps* correctly decided the case, but whether the Supreme Court overruled *Stamps*." 12a n.5.

The court of appeals "immediately conclude[d]" that *Lohr* neither explicitly overrules *Stamps* nor "implicitly requires us to disregard *Stamps* as controlling precedent." 12a. It then considered whether the state-law duties upon which petitioners'

damages actions rely were the kinds of requirements targeted for preemption under section 360k(a). The court recognized the *Lohr* majority's view that claims based on state product liability duties generally "escape preemption ... because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with-respect to' specific devices such as pacemakers." 14a (quoting *Lohr*, 518 U.S. at 501, in turn quoting 21 U.S.C. 360k(a)). It acknowledged that it was "plainly bound" to follow a majority opinion of this Court (15a), but it did not feel so constrained here, because it read Justice Breyer's joinder in it as limited to the 510k substantial equivalence process at issue in *Lohr*, not the PMA process at issue in *Stamps*. 16a. The court of appeals thus adhered to *Stamps*'s holding that product-liability claims alleging defects in a medical device "create specific requirements under state law." 16a. The Fifth Circuit did not consider the FDA's preemption regulation, 21 C.F.R. 808.1(d), which, like the *Lohr* majority opinion, states that state-law requirements of "general applicability" are not preempted under section 360k(a).

The court then addressed the question whether the PMA process imposes specific preemptive requirements. 21a. *Stamps* controlled, the court held, because it concerned the PMA process while *Lohr* dealt with what it termed the less "specific" 510k process. Having thus decided that "*Lohr* does nothing to upset *Stamps*'s binding authority" (22a), the Fifth Circuit concluded that all of petitioners' tort claims are preempted.

REASONS FOR GRANTING THE WRIT

A. This Court's Guidance Is Needed To Resolve A Deep Post-*Lohr* Division Among The Federal And State Appellate Courts.

The decision below illustrates a deep post-*Lohr* split in authority in two important and related respects. First, the decision below widens the division among the federal circuit courts and state courts of last resort on the issue that was determinative in the court below: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design and manufacture the device and failed to warn of the device's inadequacies. Some courts, including the Eleventh Circuit, hold that PMA does not trigger preemption under section 360k(a) and that, therefore, state-law damages actions alleging injuries caused by PMA devices are not preempted. Other courts agree with the Fifth Circuit that PMA does, in fact, trigger preemption. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), *pet. for cert. pending*, No. 00-1766 (filed May 24, 2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (same), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). As explained below in Part B, petitioners believe that the no-preemption rulings are better reasoned because they are truer to the text and purpose of section 360k(a) as construed by this Court in *Lohr*. For present purposes, however, the key point is that there is substantial conflict on an important and recurring issue of federal law that is significant to medical device patients, the industry that makes

those devices, and the federal agency that regulates them.

Second, the courts of appeals and the state appellate courts are divided in their application of the analytic framework set forth in *Lohr* for resolving express preemption questions under 21 U.S.C. 360k(a). As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. 808.1(d).

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. 360k(a), the federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. 801.430), in contrast to the comprehensive, but general, good manufacturing and labeling regulations that the Court held did not have preemptive effect. 470 U.S. at 497-99. In his concurrence, Justice Breyer suggested that an example of this type of specific federal requirement would be an FDA rule that a particular hearing-aid component be built with two-inch wires. *See id.* at 504.

Although the FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner, the Fifth Circuit nonetheless held, based on its prior ruling in *Stamps*, that the PMA process was a "specific" requirement as applied to the FDA's review of the 4004 lead. 21a. *Accord, e.g.*, *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887-

88 (Cal. App. 1997). But as the Fifth Circuit recognized in citing the Eleventh Circuit's ruling in *Goodlin* (12a n.5), other appellate and trial courts have come to the opposite conclusion, holding that the PMA process itself is not a specific requirement under *Medtronic*. *Goodlin*, 167 F.3d at 1373-77; *Weiland*, 721 N.E.2d at 1152-53; *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996); *Haidak v. Collagen Corp.*, 67 F. Supp.2d 21, 23-24 (D. Mass. 1999) (*Lohr* effectively overrules pre-*Lohr* First Circuit decision ascribing preemptive effect to PMA); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997).[3]

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit below

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[3]Similarly, two state Supreme Courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. 360j(g)) — which is often a precursor to the PMA process — are not preempted because that process does not establish specific requirements under *Medtronic*. *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997). *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075 (1998) (investigational device process does establish preemptive federal requirements). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and claiming that PMA and investigational processes are comparable).

acknowledged *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices, and understood that it would, if applied to these cases, require a ruling in favor of petitioners. 14a-16a; *see also Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). The court of appeals did not follow that majority holding, however, on the ground that it is incompatible with Justice Breyer's *Lohr* concurrence. 14a; *see also Papike*, 107 F.3d. at 742; *Mitchell*, 126 F.3d at 912; *Papike*, 107 F.3d at 742; *Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887 (Ct. App. 1997); *Fry*, 695 A.2d at 517. As discussed below (at 21-22), these appellate courts erred in applying *Lohr*'s majority holding. On the question whether this Court should grant review, however, the significance of these rulings is that they are at odds with the decisions of other appellate courts that have held that this Court meant what it said in *Lohr*: State laws of general applicability are not among those laws targeted for preemption by section 360k(a).

For instance, in *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every

> manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

Id. at 789 (quoting *Lohr*, 470 U.S. at 501) (internal citations omitted).

Other appellate courts have come to the same conclusion. *See Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686 (same); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div. 1997), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App.) ("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996)(same), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *see also Quillen*, 1997 U.S. Dist. Lexis 6974, *17-*18 (same).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.[4]

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[4]The split in authority is particularly problematic in (continued...)

B. The Decision Below Cannot Be Reconciled With *Lohr*.

Review should also be granted because the Fifth Circuit's serious misinterpretation of *Lohr* leaves consumers injured by PMA devices without a damages remedy. In that regard, the court below erred in two fundamental ways.

First, the mere issuance of PMA is not a specific preemption-triggering requirement under section 360k(a). Although the PMA process is often more rigorous than the marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences); *see also Buckman Co. v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012, 1015 (2001), it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed,

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[4](...continued)
Illinois, where, if the complaint is filed in, or removed to, federal court, the plaintiff's claims are preempted, *see Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998), but if the complaint remains in state court, there is no preemption. *See Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999). The same situation exists in Kentucky. *Compare Kemp*, 231 F.3d 216 and *Martin*, 105 F.3d 1090 (broad preemption holdings applicable to cases filed in federal courts in Sixth Circuit), *with Niehoff*, 950 S.W.2d 816 (no-preemption ruling of Kentucky Supreme Court). A similar problem arises in California, where the state's own appellate courts are in conflict. *Compare Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996) (no preemption), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997), *with Steele v. Collagen Corp.*, 63 Cal. Rptr. 879 (Cal. App. 1997) (preemption).

manufactured, or labeled. As the Eleventh Circuit in *Goodlin* explained, although the PMA process "differs in significant ways from the 510k process at issue" in *Lohr*, 167 F.3d at 1374, the result regarding preemption is the same: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Id.* at 1376; *see also id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus also not preemptive). Thus, the PMA process contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. 801.420), or to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 470 U.S. at 504. Indeed, as the Solicitor General has noted, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, not with the FDA. Brief for the United States as Amicus Curiae in *Smith Indus. Med. Sys., Inc. v. Kernats* ("United States Brief in *Kernats*"), No. 96-1405, at 16 (U.S. filed Dec. 10, 1997);[5] *cf.*

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[5]In *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, in responding to this Court's request for advice on the same issue presented by this petition, the Solicitor General took the position that FDA pre-market approval does not preempt state-law damages claims. United States Brief in *Kernats*, at 14-18. The Solicitor General explained that "[t]he current division among the lower courts ... would normally provide a strong justification for this Court to grant review and definitively resolve the conflict," but recommended that review be denied because the state appellate court decision in *Kernats* was not final under 28 U.S.C. 1257. *Id.* at 10-14. He also

(continued...)

American Airlines, Inc. v. Wolens, 513 U.S. 219, 228-29 (1995).

Second, the decision below misapprehends *Lohr* in holding that petitioners' claims — and, therefore, all traditional damages claims involving a PMA device — are preempted, even though they are, without dispute, premised on state-law duties of general applicability. 3a (referring to general state-law duties on which petitioners rely); *see Lohr*, 470 U.S. at 501-02; *see also* United States Brief in *Kernats*, at 17-18 (state-law claims regarding PMA devices premised on duties of general applicability not preempted under *Lohr*). Of particular importance, the court of appeals did not mention, let alone apply, the FDA's longstanding preemption regulation, 21 C.F.R. 808.1, even though it is directly applicable here. That regulation, which was accorded substantial weight in *Lohr*, 470 U.S. at 496; *see id.* at 505-06 (Breyer, J., concurring), provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to

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[5](...continued)
noted that the pendency of a proposed FDA interpretive rule regarding preemption provided another reason to deny review. *See id.* at 19-20. That proposed rule has since been withdrawn. *See* Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2 (U.S. filed June 7, 2000) (petition stage). Since the Solicitor General's December 1997 filing in *Kernats*, the division among the lower courts, and thus the need for this Court's guidance, has become much more pronounced, because of the subsequent issuance of the no-preemption decisions of the Eleventh Circuit in *Goodlin* and the Illinois Supreme Court in *Weiland*, and the decision below, among others.

devices (e.g., requirements such as general electrical codes, and Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices ...." 21 C.F.R. 808.1(d)(1). The FDA's regulation encompasses petitioners' general state-law claims and explicitly refers to one of them — the Texas Deceptive Trade Practices Act, an "unfair-trade practices" law of general applicability.

As noted earlier, the Fifth Circuit disregarded the *Lohr* majority's analysis in reliance on Justice Breyer's concurrence. The simple answer, of course, is that a lower court has no warrant to disregard a majority holding of this Court. In any event, the Fifth Circuit's view is inconsistent with Justice Breyer's concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 470 U.S. at 504 (Breyer, J., concurring). Petitioners' state-law damages claims, however, based on general Texas law duties to properly design and manufacture a product and to warn of its inadequacies, do not involve a specific state-law requirement of this kind, and thus their claims do not present the kind of direct conflict that concerned Justice Breyer.

In sum, review should be granted because the ruling below is at odds with this Court's decision in *Lohr*.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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September 2001

APPENDIX

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 99-41089

BILLYE JEANNE MARTIN,
Plaintiff-Appellant,

versus

MEDTRONIC, INC.,
Defendant-Appellee.

No. 99-41090

LIBRA SALAZAR,
Plaintiff-Appellant,

versus

MEDTRONIC, INC.,
Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

June 18, 2001

Before REYNALDO G. GARZA, JOLLY, and HIGGINBOTHAM, Circuit Judges.
E. GRADY JOLLY, Circuit Judge:

In this consolidated appeal,[1] we address a question of federal preemption: whether, based on Medtronic's compliance with the Food and Drug Administration's ("FDA") rigorous premarket approval procedure ("PMA"), the plaintiffs' Texas common law products liability tort claims are preempted by 21 U.S.C. § 360k, the Medical Devices Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). We have addressed this issue before. In Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5th Cir. 1993), we held that similar state product liability claims were preempted. Since we decided Stamps, however, the Supreme Court has spoken on the issue. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). The Supreme Court did not specifically decide the case before us, yet spoke in a way that overruled Stamps in part. Lohr is a difficult opinion to apply in this case; first, because it involves a process far less specific in its requirements than the PMA process involved in both this case and Stamps, and second, because on points important to this appeal, the Lohr court was fractured. In any event, we ultimately determine that for purposes of deciding this appeal, Stamps is binding precedent that controls the outcome of the case. Accordingly, we hold that the Texas state product liability claims in this case are preempted by the MDA, and we affirm the judgment of the district court dismissing the complaint.

I

Billye Jeanne Martin and Libra Salazar each claim that they were injured by Medtronic's defective pacemaker (Model

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[1]The cases have been consolidated for the purposes of appeal only. The appellants, however, brief their appeal as if the district court considered their cases on a consolidated basis. Therefore, we treat the procedural history in the same manner.

4004). They allege that the pacemaker contained a defective "ventricular lead," the wire that carries current into the heart muscle. Their product liability claims include negligence, gross negligence, strict liability, breach of warranty, and violation of the Texas Deceptive Trade Practices Act; all claims are based on alleged deficiencies in the safety and effectiveness of the design, manufacturing process, warnings, and labeling of the lead.

The district court initially granted Medtronic's motion for summary judgment only in part, finding that the MDA preempted Salazar's and Martin's design, manufacturing process, and warning claims. The district court reasoned that in all these areas, the FDA, through its PMA procedure,[2] had approved Medtronic's product. The district court, however, denied summary judgment on the plaintiffs' claims that Medtronic had deviated from FDA requirements. Following further discovery, Medtronic renewed its summary judgment motion. The district court then granted the renewed motion, finding that appellants failed to produce evidence of alleged deviations, and entered judgment dismissing each complaint. These appeals, now consolidated, present the single issue of whether the FDA's PMA procedure preempts the state law tort claims.

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[2]Under the FDA's PMA process, the manufacturer of the medical device must submit a detailed application to the FDA, including information on product specifications, manufacturing, intended use and proposed labeling. Qualified experts review each application and prepare a report and recommendation. The FDA then has six months to accept or reject the application. See 21 U.S.C. § 360e; Stamps v. Collagen Corp., 984 F.2d 1416, 1419 (5th Cir. 1993).

II

We begin our consideration of this question of preemption by making a few preliminary observations that serve to place in context the even more precise issue before us--to what extent is our case today decided by precedents of this court and the Supreme Court. The MDA classifies medical devices into three categories based on the degree of risk they pose to the public. Class I devices pose little or no risk to public health and are subject only to general controls on manufacturing. Class II devices are potentially more harmful and may be subject to regulations and product specifications. Class III devices, the most strictly regulated, are "[d]evices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.'" Lohr, 518 U.S. at 477 (quoting 21 U.S.C. § 360c(a)(1)(C)).

A pacemaker is classified as a "Class III" medical device. As such, it must undergo an indisputably thorough, rigorous, and costly premarket review (some 1,200 FDA man-hours at hundreds of thousands of dollars in cost) by the FDA. Under this PMA process, the manufacturer must give the FDA a "reasonable assurance" that the product is safe and effective. Although this term does not sound excessively demanding, the PMA process is rigorous. It requires manufacturers to submit detailed information regarding the safety and efficacy of their devices. This includes, among other things, full reports of all information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. See 21 U.S.C. § 360e(c)(1) (describing the components of a PMA application). The FDA then reviews the

application, spending an average of 1,200 hours on each submission before granting marketing approval. The statutory basis for this process, and its exceptions, are set forth at length in Lohr, 518 U.S. at 477, and need not be reiterated here.

It is central to our resolution of this appeal that we have held that § 360k preempts these state products liability claims when the device manufacturer complies with the FDA's PMA process. See Stamps, 984 F.2d at 1422. In this appeal, it is not disputed that Medtronic has complied with the FDA's PMA process in the creation of its pacemakers. Thus, based on the holding of Stamps, the claims here should be preempted.

But yet there is a twist. After Stamps, the Supreme Court considered the scope of MDA preemption of state law claims in the "§ 510(k) notification" process,[3] an exception to the far more demanding PMA review process. See Lohr, 518 U.S. 470. The § 510(k) process allows improvements to existing devices to be rapidly introduced into the market by foregoing the extensive review in the PMA process. Id. at 478. While the PMA process requires an inquiry into the risks and efficacy of each device through a variety of reports and submissions, as described above, the § 501(k) process only requires the manufacturer to show that the device is "substantially equivalent" to devices already on the market. Under the § 501(k) process, the manufacturer must submit proposed labeling, labels, and advertisements that describe the device, its intended use and the directions for its use; a statement indicating how the device is similar to or different from comparable products; a statement that the submitter believes that the information is accurate and complete; and any

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[3]The section number refers to the original section of the MDA containing the provision.

additional information necessary for the FDA Commissioner to make a determination as to whether the device is "substantially equivalent." See Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 1016, 148 L.Ed.2d 854 (2001); 21 C.F.R. §§ 807.87, 807.92. The manufacturer does not have to submit information on the safety or efficacy of the device. In contrast to the 1,200 hours that it takes to complete a PMA review, a § 510(k) review takes an average of 20 hours. Lohr, 518 U.S. at 479. As the Supreme Court has noted, "[t]he § 510(k) notification process is by no means comparable to the PMA process." Id. at 478-79.

Lohr, however, is highly relevant to this appeal because it considered in some detail the preemption statute that is applicable both to the § 510(k) process and the PMA process. Notwithstanding its relevance, the Supreme Court decision must be more than merely illuminating with respect to the case before us, because a panel of this court can only overrule a prior panel decision if "such overruling is unequivocally directed by controlling Supreme Court precedent." United States v. Zuniga-Salinas, 945 F.2d 1302, 1306 (5th Cir. 1991). This means that Stamps should apply to this case unless "an intervening Supreme Court case explicitly or implicitly overrul[es] that prior precedent." United States v. Short, 181 F.3d 620, 624 (5th Cir. 1999). Thus, the first, and ultimately only, question we face is the degree to which Stamps retains precedential value after the Supreme Court's decision in Lohr.

A

To resolve the impact of Lohr on our precedent in Stamps, we begin by setting out the relevant statutory and regulatory language that we must consider. Section 360k(a) ("General Rule") is the preemption provision of the MDA governing the extent to which the MDA preempts state law. It

applies both to situations arising under the § 510(k) process and the PMA process. It states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA has promulgated regulations interpreting § 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

B

With both the statute and the regulations in mind, we turn to consider the intervening Supreme Court decision, Medtronic Inc. v. Lohr, 518 U.S. 470. In Lohr, the Supreme Court considered whether state tort claims were preempted when the FDA subjected the medical device to § 510(k) notification under the MDA, a process, as we have noted, far

less thorough than the PMA process presented in this case.[4] In a five to four decision, the Court held that the state tort claims in that § 510(k) case were not preempted. The Court, however, fractured over the question of whether the preemption section of the MDA would ever preempt general state law tort claims.

The facts underlying the plaintiffs' claims in Lohr are similar to the facts in our case: Lohr and her husband sued on state law claims over a defective lead in a pacemaker. Their complaint alleged both negligence and strict liability claims for defective design, failure to warn, and negligent manufacturing. Unlike our case, however, which involves a rigorous review under the PMA process, Medtronic began marketing the pacemaker lead in Lohr after the FDA had found only that the device was "substantially equivalent" to devices already on the market under § 510(k). Indeed, the FDA itself "emphasized ... that [the § 510(k) notification process] should not be construed as an endorsement of the pacemaker lead's safety." Lohr, 518 U.S. at 480.

The Court's reasoning largely focused on the requirements of the FDA's regulation interpreting § 360k, cited

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[4]As the Supreme Court itself has observed, the PMA process and the § 510(k) process are clearly distinguishable. See Lohr, 518 U.S. at 493 (noting that substantially equivalent devices have "never been formally reviewed under the MDA for safety or efficacy" and that the FDA does not consider the § 510(k) process "official FDA approval"); Buckman, 121 S.Ct. at 1017 ("Admittedly, the § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.").

and quoted earlier in this opinion. The Court observed that certain factors must be present, according to the regulations, before § 360k would preempt state requirements. First, there must be a state requirement specifically developed with respect to medical devices that is different from or in addition to federal requirements. Second, the state requirement must relate to the safety or effectiveness of the device, or "'other matter included in a requirement applicable to the device.'" Lohr, 518 U.S. at 500 (quoting 21 U.S.C. § 360k(a)). State requirements of "'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement for a specific device.'" Id. Third, the federal requirement must be specific to the particular device. The Court held that because neither the federal requirements relating to the § 510(k) notification procedure nor the state common law requirements were specific to the device, Lohr's tort claims were not preempted.

Although the Court concluded that Lohr's tort claims were not preempted, the majority split on the broader question of whether the duties enforced by common law actions could ever be "requirements" for the purpose of preemption. The four justice plurality written by Justice Stevens, distinguishing the MDA from the statute in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), found that general common law actions were not the "requirements" that Congress was concerned about when it enacted the preemption provision. Thus, Justice Stevens concluded that "§ 360k(a) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." Lohr, 518 U.S. at 491. That, however, was only a plurality.

The meaning of Lohr as applied to our case becomes confusing at this point. Concurring with only parts of the

majority writing, Justice Breyer found that the MDA could in fact preempt state tort suits. Relying on Cipollone, in which the "Court made clear that similar language 'easily' encompassed tort actions," he reasoned that a state requirement that takes the form of a duty of care is essentially no different from a state statute or regulation. Id. at 504 (Breyer, J., concurring). Justice Breyer noted, however, that the FDA promulgated a regulation that allows preemption when there are "'specific [federal] requirements applicable to a particular device.'" Id. at 506 (quoting 21 C.F.R. § 808.1(d) (1995)). Because the FDA requirements relating to design, manufacturing and labeling in the § 510(k) notification process at issue in Lohr were "not 'specific' in any relevant sense," Justice Breyer concluded that the FDA did not intend the § 510(k) notification procedures to preempt state tort claims. Id. at 507.

The four justices concurring in part and dissenting in part, relying on the § 360k preemption language and not the FDA's regulations, concluded that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509 (O'Connor, J., concurring in part, dissenting in part). Justice O'Connor noted that a majority of the Court in Cipollone agreed that state common law damages actions do impose "requirements," and that the rationale behind that decision was equally applicable in Lohr. Id. at 510. Thus, given Justice Breyer's concurrence, five justices would agree that state common law actions do impose "requirements" that can be preempted under the statute, as found in Cipollone.

Because only parts of Justice Stevens's opinion commanded a majority, extracting the final meaning of Lohr is no easy task. Assessing Lohr in the light of the three requirements for preemption described above, the Court first held that general common law duties do not impose

requirements that are different from or in addition to the § 501(k) process. The Court offers no clear guidance on when the common law may satisfy the second factor, that is, that the state requirement relate to the safety or effectiveness of the device or establish a "substantive requirement" for a specific device. Although Justice Breyer's concurrence very specifically disavows the view that common law duties cannot provide substantive requirements for the purpose of preemption, neither his concurrence nor the plurality opinion offers much help to us in developing the point. As to the third factor, the Court held that the FDA's "substantially equivalent" determination under the § 501(k) process is not a federal regulation specific to a particular device, at least under the facts of Lohr. Because these holdings do not explicitly or implicitly decide the case before us, we must compare Lohr with Stamps, the circuit precedent that we are required to follow.

C

Our decision in Stamps, 984 F.2d 1416, which relies on Cipollone and predates Lohr, held that state tort claims in that case were preempted under the MDA. In Stamps, the plaintiff contracted a rare autoimmune disease from being injected with defendant's Class III products. She then filed suit alleging defective design, inadequate warnings, and negligent failure to warn. Because the FDA scrutinized the labeling, design, and manufacturing of a product during the PMA process, we determined that each of these state claims covered an area stringently regulated by the FDA.

We then addressed the question of whether state tort claims could be considered state "requirements" under § 360k. Relying on the Supreme Court's preemption doctrine as laid out in Cipollone, 505 U.S. 504, we noted that the term "requirements" in § 360k(a) "'sweeps broadly' and encompasses

common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. Thus, the specific duties in Texas tort liability create requirements in addition to the strict requirements of the Class III PMA process. Stamps concluded that "[s]tate tort causes of action--to the extent they relate to safety, effectiveness, or other MDA requirements--constitute requirements 'different from, or in addition to' the Class III process; they are, therefore, preempted." Stamps, 984 F.2d at 1424.

III

When we turn to consider the impact of Lohr on the precedential effect of Stamps, we can immediately conclude that the Supreme Court did not explicitly overrule the case. Neither do we think that Lohr implicitly requires us to disregard Stamps as controlling precedent.[5] Although Stamps gave § 360k a

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[5]In fact, after Lohr, both the Sixth and the Seventh Circuits determined that the PMA process constitutes specific federal requirements that preempt state tort suits. Kemp v. Medtronic, 231 F.3d 216, 226-227 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997). These decision parallel our reasoning in Stamps. Although not all courts have found that common law tort suits relating to the device are preempted by the PMA process, see Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999) (finding that plaintiffs' state law tort claims were not preempted by Medtronic's compliance with the FDA's PMA process), Brooks v. Howmedica, Inc., 236 F.3d 956 (8th Cir. 2001) (finding that the PMA process constitutes specific federal requirements and common law tort suits can constitute specific state requirements but finding no conflict between them), vacated and reh'g en banc granted by 246 F.3d 1149 (8th Cir. 2001), our question is

somewhat broader preemptive scope than the Supreme Court's opinion in Lohr,[6] none of the components of the preemption test in Lohr contradict the holding in Stamps as applied here. As noted above, the Supreme Court held that for preemption under § 360k, there must be a state requirement--which does not exclude common law tort duties--with respect to a medical device that relates to the safety or efficiency of a device, or establishes a substantive requirement for the device, that is different from or in addition to a specific federal requirement. Lohr, 518 U.S. at 500. Stamps is not contrary to these criteria.

A

First, Stamps found that common law tort suits can impose state requirements for the purposes of preemption. Stamps, 984 F.2d at 1423. Although not part of the holding of Lohr, a majority of the justices in Lohr clearly agreed with this proposition. See 518 U.S. at 509 ("I conclude that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ

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not whether the panel in Stamps correctly decided the case, but whether the Supreme Court overruled Stamps. As long as Stamps is not inconsistent with the law set out in Lohr, this panel has no authority to overrule it.

[6] For instance, Stamps notes that "section 360(k). . . 'sweeps broadly' and encompasses common law tort actions within its preemptive scope." Stamps, 984 F.2d at 1421. In contrast, Lohr remarks on the FDA's "narrow understanding" of § 360k and finds that "it is impossible to ignore [the statutory and regulatory language's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." Lohr, 518 U.S. at 500, n. 18.

from those imposed by the FDCA")(O'Connor, J., dissenting). Id. at 503 ("[T]he MDA will sometimes pre-empt a state-law tort suit.")(Breyer, J., concurring). Thus, it seems clear that Lohr did not overrule our holding in Stamps that state tort suits can constitute specific state requirements for the purposes of preemption.

B

Second, Stamps found that common law duties could be preempted "to the extent that they relate[d] to safety, effectiveness, or other MDA requirements." Stamps, 984 F.2d at 1423. With some similarity, Lohr observed that state requirements must, "with respect to" medical devices, establish a "substantive requirement for a specific device," and must relate to the "safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Lohr, 518 U.S. at 500. The Lohr majority opinion did not articulate when common law requirements may become "substantive requirements" or under what circumstances they are considered to be "specifically developed 'with respect to' medical devices." Id. at 501. To determine whether Stamps's understanding of common law duties as state requirements is consistent with Lohr, we must therefore consider Justice Stevens's opinion in the light of Justice Breyer's concurrence.

Justice Breyer joined in the majority's finding that "general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," and that "these state requirements escape preemption . . . because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." Lohr, 518 U.S. at 501. Justice Breyer's separate concurrence, however, which recognizes that common law tort suits may be preempted, does not support a conclusion

that common law claims are invariably too general for preemption. Indeed, Justice Breyer noted that he "basically agree[d] with Justice O'Connor's discussion" of whether the MDA can preempt a state law tort suit Id. at 503, which observed that "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." Id. at 509. Furthermore, Justice Breyer specifically disavowed the portions of the opinion finding that "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device,'" Id. at 502 (plurality) (citing CFR § 808.1(d)(6)(ii)(1995)), and that the term "'[r]equirement appears to presume that the State is imposing a specific duty on the manufacturer." Id. at 487. As noted by the Ninth Circuit, these apparently conflicting positions make analysis difficult:

> [I]t makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements.

Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997).

Of course, we are plainly bound to follow the majority opinion in Lohr; yet, we cannot fully grasp the opinion's interpretation of when state common law requirements are considered "specifically developed with respect to medical devices" without Justice Breyer's concurrence. The majority opinion says that general common law obligations are not a threat to federal requirements. Id. at 501. Justice Breyer joins in the opinion, but, in his concurrence, he points out that these

general common law requirements are not a threat because there is no potential for them to conflict with the federal requirements at issue in Lohr, namely, the requirements under the § 501(k) process. He also notes that while common law duties may seem general, they can result in the imposition of standards that are very device-specific. Justice Breyer takes the position that there is no preemption in Lohr because there is no conflict between the § 501(k) process and general common law duties. See Lohr, 518 U.S. at 508 (Breyer, J., concurring)("I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit"). Justice Breyer's emphasis on the juxtaposition of the state and federal duties suggests that the Court would be less sanguine about the generality of common law duties if the federal requirements were specific, say, as in the PMA process.[7]

We think it is important to read the portion of the majority opinion addressing specific state requirements narrowly to avoid adopting as controlling law the broadly worded plurality opinion. Using Justice Breyer's concurrence as a guide, we can conclude only that general duties of care can generate specific requirements that conflict with specific FDA requirements. We read Justice Breyer's special concurrence to

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[7]Justice Breyer even notes that "it is possible that the plurality also agrees" that

> insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Lohr, 518 U.S. at 504-05 (Breyer, J. concurring). This observation suggests that it was important to Lohr's conclusion that both state and federal requirements were general.

recognize that, although a manufacturer's general duty of care to avoid foreseeable dangers may be too general to merit preemption when there is no specific federal requirement, the proof required to establish a particularly alleged common law claim can be specific enough that the claim becomes preempted as an "additional" or "different" requirement than the FDA requirement.[8] This reasoning is consistent with the majority opinion; while the general duty, standing on its own, is not a threat to federal requirements and is not developed specifically "with respect to" medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements. Because the federal § 510(k) requirements were not specific, it was unnecessary in Lohr to reach that conflict. For instance, as an example of a general common law duty, the majority opinion uses a "general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." Id. at 501. While this duty does not seem "developed with respect to" a medical device specifically, proving a violation of that duty would require a jury to determine precisely what information users should have been provided. Those determinations would not conflict with the § 510(k) process, because that process does not determine or approve what information consumers of the product should be provided. On the other hand, however, a jury's determination may directly conflict with FDA determinations and approvals made during the PMA review process.

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[8]However, common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted. See Lohr, 518 U.S. at 495.

Thus, reading the language in the majority opinion through the lens of Justice Breyer's concurrence, we cannot say that Lohr overruled the holding of Stamps that common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law. After Lohr, however, we need to consider more than whether the common law duties relate to safety, effectiveness, or other MDA requirements; we need to focus on whether the specific requirements imposed by those common law duties threaten to interfere with specific federal requirements.

C

Third, Stamps interpreted state tort causes of action as requirements "different from, or in addition to" the PMA process, thereby meriting preemption. Stamps, 984 F.2d at 1423. This holding reflects a comparison of state and federal requirements and a consideration of how additional state common law requirements could undermine the FDA's detailed PMA review process. On the other hand, Lohr compared common law duties with the § 510(k) process, which imposes relatively minor disclosure requirements, and found that preemption was not appropriate. Given the difference between the intensive PMA review and the minimal requirements under the § 510(k) process, Lohr does not call into question the holding of Stamps, that common law duties can impose requirements different from or in addition to the PMA process.

Stamps, however, specifically disagreed with the proposition that "the lack of direct conflict between the state and federal regulations compel[led] a finding of no preemption." Id. at 1424. On the other hand, this proposition seems to have been adopted by the Supreme Court; Lohr notes that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when

those duties parallel federal requirements." Lohr, 518 U.S. at 495. This language tells us that tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted. Indeed, that is precisely what the district court held in this case, and that holding has not been appealed. In the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted. Thus, Lohr narrows the language in Stamps's preemption analysis to allow for state actions that parallel federal requirements. This holding of Lohr, although overruling Stamps in that specific matter, does not, however, overrule Stamps as it applies to the case before us.

D

Fourth, Stamps held that the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption.[9] Here, too, there is no conflict with Lohr. Although Lohr considered the application of the identical FDA regulation governing labeling, the labeling requirements in Lohr under the § 510(k) process were general; as it did not go through the PMA process, the labeling in Lohr was not specifically reviewed by the FDA.

On its face, therefore, Lohr is limited to a finding that

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[9]During the PMA process, the FDA reviews the proposed labeling as well as the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device. 21 U.S.C. § 360e(c)(1)(B)-(C),(F). If any element of the manufacturing does not comply with regulations, or labeling is found to be false or misleading, the application for approval is denied. Id. § 360e(d)(2)(A)-(D).

the § 501(k) process does not create specific federal requirements that conflict with state tort actions. Indeed, the plurality's opinion itself seems to leave this suggestion when it notes at several points in the course of its writing the very significant differences between the FDA's § 510(k) approval and a PMA approval. See, e.g., 518 U.S. at 492-94 (noting that the § 510(k) process "is focused on equivalence, not safety. As a result, substantial equivalence determinations provide little protection to the public") (internal quotations and citations omitted).[10] The PMA is specifically focused on safety and requires a significant weighing of considerations specific to the device before approval is granted. Thus, the fact that the § 510(k) process did not preempt state causes of action in Lohr does not indicate that the PMA process cannot preempt state tort causes of action.

Thus, for all these reasons, we are fully convinced that Stamps has not been overruled and remains viable authority in this circuit to the extent that we have described. Instead of overruling Stamps, Lohr should be read to implicitly affirm our holding in Feldt v. Mentor Corp., 61 F.3d 431 (5th Cir. 1995), in which we reached the same conclusion as did the Court in Lohr, that the § 510(k) process did not create preemptive "requirements." 518 U.S. at 484 n.6.[11] We think that our separate preemption treatment of the differing processes to

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[10]See also id. at 480 ("The agency emphasized, however, that this determination [of substantial equivalence] should not be construed as an endorsement of the pacemaker lead's safety.").

[11]Our decision in Feldt explicitly discusses our decision in Stamps, 61 F.3d at 435, but, after analyzing the § 510(k) process, states, "there are, in short, no requirements or prohibitions specifically regarding the design of non-PMA Class III devices." Id. at 438.

device approval is further reflection and acknowledgment of the fact that the PMA process is of an order that is a magnitude apart from § 510(k) approval.

In sum, we simply cannot read Lohr as establishing a new rule of law that contradicts our preexisting case law as it applies in this appeal. Thus, although the broad holding of Stamps that the PMA process preempts state tort causes of action to the extent that they relate to safety, effectiveness or other MDA requirements is narrowed by Lohr's finding that preemption requires substantive requirements imposed by common law duties to threaten federal requirements, Stamps remains controlling precedent for the purpose of this appeal.

IV

We turn now to apply Stamps, as narrowed by Lohr, to the case before us. The plaintiffs allege that Medtronic breached state law duties by designing a pacemaker lead that contained certain materials, by labeling the lead with certain warnings, and by manufacturing the lead in a certain way. The design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process. Like the inadequate labeling, failure to warn, and defective design claims in Stamps, the plaintiffs' claims that the district court found to be preempted relate to areas specifically covered in the PMA process, and seek to impose requirements that are different from and, indeed, conflict with the PMA process.

The district court specifically found those claims that paralleled the federal process--the claims that Medtronic did not adequately comply with the PMA process--were not preempted under § 360k. This finding comports with Lohr, that general duties of care that parallel federal requirements are not

"different from, or in addition to" federal requirements, and are therefore not preempted. In Stamps, our circuit spoke to the precise question presented in this appeal. And we have concluded here that the Supreme Court's fractured ruling in Lohr does nothing to upset Stamps's binding authority as respects this particular appeal. We therefore reaffirm that a medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims brought with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval. Thus, the plaintiffs' tort law claims relating to design, manufacturing process, and failure to warn are preempted by the MDA.

V

For the reasons stated above, the judgment of the district court is

AFFIRMED.

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

BILLYE JEANNE MARTIN

V.

MEDTRONIC, INC.

CA. NO. C-96-495

ENTERED August 8, 1999

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Billye Jeanne Martin sued Defendant Medtronic in state court claiming that a ventricular lead in a pacemaker manufactured by Defendant failed after implantation and that Plaintiff suffered damages as a result. After removing the case to this Court, Defendant moved for summary judgment that Plaintiff's claims were preempted by § 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k. For the following reasons, the Court grants in part and denies in part Defendant's motion for summary judgment.

JURISDICTION

Plaintiff originally sued both Medtronic and Diagnostic

Center Hospital, Inc., the hospital at which the allegedly defective pacemaker was implanted. There was some confusion at the time the case was removed as to whether Diagnostic was domiciled in Texas, a fact which if true, would destroy diversity jurisdiction. The question became moot when Plaintiff moved to dismiss her case against Diagnostic, and the Court granted the motion. It is well-settled that a district court or appellate court may dismiss a non-indispensable party and preserve diversity jurisdiction. Newman-Green, Inc. v. Alfonzo-Lorrain, 109 S.Ct. 2218, 2223 (1989). Because diversity jurisdiction exists, the Court declines to rule on the unsettled question of whether the MDA completely preempts Plaintiffs state law claims and makes them removable to federal court. See Strong v. Telectronics Pacing Systems, Inc., 78 F.3d 256 (6th Cir. 1996) (no complete preemption); Richardson v. Advanced Cardiovascular Systems, Inc., 865 F. Supp. 210 (E.D.La. 1994) (finding complete preemption).

FACTS

A pacemaker manufactured by Medtronic was implanted in Plaintiff on December 3, 1989. On August 29, 1994, Plaintiff began to feel lightheaded and faint. Testing revealed a failure of the ventricular lead, a part of the pacemaker which is designed to transmit small electrical pulses to the heart from a pacemaker pulse generator and return signals from the heart to the pulse generator. The type of ventricular lead used in this particular pacemaker was known as a Model 4004. Plaintiff has stipulated that her lawsuit involves only alleged defects in the Model 4004 lead.

The Court finds that the Model 4004 lead received pre-market approval (PMA) from the FDA. This is the most rigorous scrutiny that a product can undergo at the FDA. The process began on March 26, 1982, when Medtronic submitted

an Investigatory Device Exemption application to the FDA requesting permission to clinically investigate the Model 4003 lead, which is similar to the Model 4004 lead.[1] This application was granted, and the investigation was conducted over four years. On September 30, 1983, Medtronic submitted a PMA application to the FDA for the Model 4003, and this was approved on July 26, 1986.

The information that was reviewed by the FDA included the results of all tests which had been performed on the Model 4003, including animal testing. Also included were engineering drawings of the device and a description of the manufacturing process that would be used. Finally, the application contained all of the proposed product labels, technical manuals and package labeling which were to be distributed with the Model 4003.

On July 18, 1988, Medtronic applied for pre-market approval of the Model 4004 lead as a supplemental application to the PMA used for the Model 4003. The PMA supplement included much of the same information which was included in the PMA for the Model 4003. The supplement stated that human testing was not necessary for the Model 4004 because animal testing had already demonstrated performance equivalent to the Model 4003, for which human tests had already been submitted. The FDA approved the Model 4004 PMA supplement on February 10, 1989.

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[1]The main difference is that the Model 4004 lead is bipolar. In addition, the Model 4004 has thicker insulation and several other modifications which are described in the affidavit of Charles Swanson. See Defendant's Motion for Summary Judgment.

Although Plaintiff contests that this process constituted an approval by the FDA of the design and manufacturing processes for the Model 4004 lead, she has come forth with no evidence to support this assertion. Defendant has presented an affidavit and numerous letters from the FDA to support its assertion that the Model 4004 lead received full PMA review. In light of this evidence, the Court finds that Plaintiff has failed to demonstrate any genuine factual dispute. The Court therefore finds that the Model 4004 lead received full PMA review and that its design, labeling, and manufacturing processes were approved by the FDA.

DISCUSSION

1. THE PREEMPTIVE EFFECT OF THE MDA

The Medical Device Amendments were added to the Food, Drug, and Cosmetics Act in 1976 in order to allow the FDA to regulate medical devices. The strictest FDA regulation is reserved for Class III devices which are defined as devices which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health, or (2) present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). In order to market a Class III device in the United States, the manufacturer must obtain pre-market approval from the FDA, which requires "reasonable assurances of [the product's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).[2] There is an

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[2]The PMA process involves a rigorous review of the ingredients, components, manufacturing methods, and proposed labeling of a medical device. 21 U.S.C. § 36Oe(c)(1)(A)-(G). The average time required for review is approximately 1200 hours. Fry v. Allergan Medical Optics, et al., 695 A.2d 511, 513

exception for devices which were already on the market when the MDA was passed, 21 U.S.C. § 36Oe(b)(1)(A), as well as devices which are substantially equivalent to those devices (the § 510k exception). 21 U.S.C. § 360e(b)(1)(B).

The MDA contains a clause which preempts certain areas of state law relating to medical devices:

> ...no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA implemented a regulation interpreting this preemption clause, which a majority of the Supreme Court in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2256 (1996) found to be entitled to substantial weight:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not

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(R.I. 1997).

> preempted by [the act's preemption clause] because they are not 'requirements applicable to a device' within the meaning of [the preemption clause]. The following are examples of State or local requirements that are not regarded as preempted by [the preemption clause]:
> (1) [The preemption clause] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or unfair trade practices in which the requirements are not limited to devices.
> (2) [The preemption clause] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), the Fifth Circuit held that the MDA preempted state law claims for defective design, inadequate warnings, and negligent failure to warn with respect to collagen implants which had undergone PMA review. The court found that the FDA scrutinizes the labeling, design, and manufacturing of a product during the PMA process, and that the plain language of the MDA preempts state law tort suits which would impose requirements different from those imposed by the FDA.

In 1996, the Supreme Court decided Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996), and shed some light on the preemptive effect of the MDA. The Court held that state law claims against Medtronic for an allegedly defective pacemaker were not preempted by the MDA. Importantly, the pacemaker at issue in that case, unlike the one currently before this Court, had not undergone full PMA review. The pacemaker in Lohr

was deemed substantially equivalent to a pacemaker already on the market when the MDA was enacted, so it was approved by the FDA under the far less rigorous § 510k exception.

The Lohr decision settled some issues. At least five Justices agreed that state law tort actions are "requirements" which the MDA can potentially preempt. 116 S.Ct. at 2259, 2262. The Court was unanimous that because the § 510k procedure says nothing about a product's safety, the FDA's § 510k approval of a product does not preempt a state law claim that the product is defectively designed. Id. at 2254, 2263-64. A majority of the Court also held that FDA Good Manufacturing Practices and labeling requirements are not sufficiently specific and do not relate only to medical devices, so they do not preempt state law claims for manufacturing defects and failure to warn. Id. at 2258. Finally, the Court was unanimous that claims for products manufactured in *violation* of FDA requirements are not preempted. Id. at 2255, 2264.

The Lohr case does not address the situation before this Court in which the allegedly defective product received the more rigorous PMA scrutiny from the FDA. This Court finds that the Lohr case is distinguishable, because as a majority of the Court stated: "[t]he 510(k) process is focused on *equivalence*, not safety." 116 S.Ct. at 2254. The PMA process is focused on safety -- PMA means that the FDA has received "resonable assurance" that a device is both safe and effective. 21 U.S.C. § 360c(a)(1)(C). Although a count of the positions of Supreme Court Justices from the concurrence and dissent is not binding, this Court also notes that at least five Justices would likely support the preemption of state law concerning a device which had gone through the PMA process.

Nearly all courts which have considered the issue in the wake of Lohr have agreed with this position. See Martin v.

Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997) (state law products liability and misrepresentation claims concerning an allegedly defective pacemaker were preempted by MDA where pacemaker had received investigational device exemption {IDE), requiring a process similar but not identical to PMA); Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (strict liability and breach of implied warranty claims concerning prosthetic hip which had received IDE were preempted, but claim that the manufacturer did not follow approved FDA procedures was not preempted); Berish v. Richards Medical Co., 937 F. Supp. 181 (N.D.N.Y. 1996) (same); Arthur Fry v. Allergan Medical Optics, et al., 695 A.2d 511 (R.I. 1997} (claims for allegedly defective intraocular lens implant which had undergone PMA review were preempted); Green v. Dolsky, 685 A.2d 110 (Pa. 1996) (same holding for collagen implants); but see Rodriguez-Suris v. Montesinos, 935 F. Supp. 71, 75 n.3 (D. Puerto Rico 1996).

The Court therefore follows pre-Lohr Fifth Circuit precedent, the implication from Lohr, and the vast majority of cases decided since Lohr, and holds that § 360k of the MDA preempts some state claims brought against the manufacturers of products which have obtained PMA from the FDA. The remaining question is which claims are preempted.

II. PLAINTIFF'S CAUSE OF ACTION

At a hearing on August 5, 1997, Plaintiff represented to the Court that she had three causes of action: (1) a claim that the pacemaker lead was unreasonably dangerous as designed; (2) a claim that the pacemaker lead was unreasonably dangerous as manufactured; and (3) a claim that Medtronic breached an implied warranty that the lead was safe and fit for the purposes for which it was intended. The Court notes that Plaintiff's original complaint makes several other claims, including a claim

for negligent failure to warn.

The Court finds that any claim challenging the design of the Model 4004 ventricular lead is preempted by § 360k and the pre-market approval of the lead by the FDA. The rigorous PMA process certainly constitutes a specific federal requirement relating to the design of the lead, and allowing a state common law suit challenging that design to go forward could impose additional and even inconsistent requirements.

The Court also finds that any claim in which the Plaintiff challenges the manufacturing processes which were approved by the FDA is preempted. Although the Court notes that the Lohr Court held that general Good Manufacturing Practices were not sufficiently specific to preempt manufacturing defect claims, here the FDA approved specific manufacturing plans as part of the PMA process. Similarly, the Court finds that any claim in which the Plaintiff challenges the adequacy of the warnings which were approved by the FDA is preempted. Although general labeling requirements are not enough to create federal preemption, here the FDA specifically approved the packaging, labels, and supplemental materials which were to accompany the lead. In fact, any change in the manufacturing or labeling that could effect the Model 4004 lead's safety and effectiveness would have required prior FDA approval. 21 U.S.C. § 36Oe(e)(1)(B),(E); 21 C.F.R. § 814.39(a).

The claims described above are preempted whether they are couched in terms of products liability, breach of warranty, negligence, gross negligence, or state law deceptive trade practices. This does not mean that all potential claims are preempted. For example, Plaintiff could claim that the manufacturing processes, specifications, or materials actually used by Medtronic were not the same as those that were approved by the FDA. The Court therefore grants the parties

120 days to conduct discovery in order to determine whether Plaintiff wishes to press any non-preempted claims.

CONCLUSION

For these reasons the Court grants in part and denies in part Defendant's motion for summary judgment. The parties are granted 120 days to conduct further discovery in order to determine whether any viable claims remain.

ORDERED this 8 day of August, 1997.

H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

BILLYE JEANNE MARTIN

V.

MEDTRONIC, INC.

CA. NO. C-96-495

ENTERED August 27, 1999

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

This is a products liability suit. Jurisdiction is proper in the Court because there is complete diversity of the parties, 28 U.S.C. 1332.

Plaintiff claims she was injured when a Model 4004M ventricular lead in a pacemaker manufactured by defendant failed after implantation. Defendant moved for summary judgment on the grounds that plaintiff's claims are preempted by § 360k of the Mdeical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. § 360k. The Court granted in part and denied in part defendant's motion because the device in question received full pre-market approval (PMA) from the FDA and, therefore, § 360k preempted some, but not all, of plaintiff's potential claims. Specifically, the Court noted

that "[p]laintiff could claim that the manufacturing processes, specifications, or materials actually used by [defendant] were not the same as those approved by the FDA," and granted additional time to conduct discovery and determine whether non-preempted claims existed. Plaintiff has not offered evidence that the processes, specifications, or materials defendant used in manufacturing the Model 4004M ventricular leads differed from the approved processes, specification, or materials. Accordingly, the Court grants defendant's renewed motion for summary judgment on this remaining issue.

In her Memorandum Brief, plaintiff suggests the Court reconsider and find her claims are not preempted by the MDA, set aside its order granting partial summary judgment, and schedule this case for trial on all claims. Plaintiff argues the Court should withdraw its previous order granting defendant's motion for summary judgment because of the United States Court of Appeals for the Eleventh Circuit's recent decision in *Goodlin v. Medtronic Inc.*, 167 F.3d 367 (11th Cir. 1999). The Eleventh Circuit found 21 U.S.C. § 360(k) does not preempt state law claims based on the failure of Medtronic Model 4004M ventricular leads. *Goodlin v. Medtronic Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999). In *Goodlin*, the Eleventh Circuit's decision was based on its finding that the PMA process did not impose specific federal requirements. Id. at 1373-1377. The Fifth Circuit has held to the contrary. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-23 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993). The Seventh Circuit has also concluded that the PMA process imposes specific federal requirements. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997), *cert denied*, 118 S.Ct. 1300 (1998). The Court follows the Fifth Circuit's conclusion in *Stamps* and the Seventh Circuit's conclusion in *Mitchell*. Accordingly, the Court denies plaintiff's motion for reconsideration.

ORDERED this 25 day of August, 1999.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

LIRBA SALAZAR

V.

MEDTRONIC, INC.

CA. NO. C-96-425

ENTERED August 8, 1999

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Lirba Salazar sued Defendant Medtronic in this Court claiming that a ventricular lead in a pacemaker manufactured by Defendant failed after implantation and that Plaintiff suffered damages as a result. Defendant moved for summary judgment that Plaintiff's claims were preempted by § 360k of the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act. 21 U.S.C. § 360k. For the following reasons, the Court grants in part and denies in part Defendant's motion for summary judgment.

JURISDICTION

The Court has diversity jurisdiction over this case pusuant to 28 U.S.C. § 1332. Because diversity jurisdiction

exists, the Court declines to rule on the unsettled question of whether the MDA completely preempts Plaintiff's state law claims and makes them removable to federal court. See Strong v. Telectronics Pacing Systems, Inc., 78 F.3d 256 (6th Cir. 1996) (no complete preemption); Richardson v. Advanced Cardiovascular Systems, Inc., 865 F. Supp. 210 (E.D.La. 1994) (finding complete preemption).

FACTS

A pacemaker manufactured by Medtronic was implanted in Plaintiff in 1990. Plaintiff alleges that the pacemaker was defective, and that she suffered personal injuries as a result. Testing revealed a failure of the ventricular lead, a part of the pacemaker which is designed to transmit small electrical pulses to the heart from a pacemaker pulse generator and return signals from the heart to the pulse generator. The type of ventricular lead used in this particular pacemaker was known as a Model 4004. Plaintiff has stipulated that her lawsuit involves only alleged defects in the Model 4004 lead.

The Court finds that the Model 4004 lead received pre-market approval (PMA) from the FDA. This is the most rigorous scrutiny that a product can undergo at the FDA. The process began on March 26, 1982, when Medtronic submitted an Investigatory Device Exemption application to the FDA requesting permission to clinically investigate the Model 4003 lead, which is similar to the Model 4004 lead.[1] This application

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[1]The main difference is that the Model 4004 lead is bipolar. In addition, the Model 4004 has thicker insulation and several other modifications which are described in the affidavit of Charles Swanson. See Defendant's Motion for Summary Judgment.

was granted, and the investigation was conducted over four years. On September 30, 1983, Medtronic submitted a PMA application to the FDA for the Model 4003, and this was approved on July 26, 1986.

The information that was reviewed by the FDA included the results of all tests which had been performed on the Model 4003, including animal testing. Also included were engineering drawings of the device and a description of the manufacturing process that would be used. Finally, the application contained all of the proposed product labels, technical manuals and package labeling which were to be distributed with the Model 4003.

On July 18, 1988, Medtronic applied for pre-market approval of the Model 4004 lead as a supplemental application to the PMA used for the Model 4003. The PMA supplement included much of the same information which was included in the PMA for the Model 4003. The supplement stated that human testing was not necessary for the Model 4004 because animal testing had already demonstrated performance equivalent to the Model 4003, for which human tests had already been submitted. The FDA approved the Model 4004 PMA supplement on February 10, 1989.

Although Plaintiff contests that this process constituted an approval by the FDA of the design and manufacturing processes for the Model 4004 lead, she has come forth with no evidence to support this assertion. Defendant has presented an affidavit and numerous letters from the FDA to support its assertion that the Model 4004 lead received full PMA review. In light of this evidence, the Court finds that Plaintiff has failed to demonstrate any genuine factual dispute. The Court therefore finds that the Model 4004 lead received full PMA review and that its design, labeling, and manufacturing

processes were approved by the FDA.

DISCUSSION

1. THE PREEMPTIVE EFFECT OF THE MDA

The Medical Device Amendments were added to the Food, Drug, and Cosmetics Act in 1976 in order to allow the FDA to regulate medical devices. The strictest FDA regulation is reserved for Class III devices which are defined as devices which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health, or (2) present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). In order to market a Class III device in the United States, the manufacturer must obtain pre-market approval from the FDA, which requires "reasonable assurances of [the product's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C).[2] There is an exception for devices which were already on the market when the MDA was passed, 21 U.S.C. § 36Oe(b)(1)(A), as well as devices which are substantially equivalent to those devices (the § 510k exception). 21 U.S.C. § 360e(b)(1)(B).

The MDA contains a clause which preempts certain areas of state law relating to medical devices:

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[2]The PMA process involves a rigorous review of the ingredients, components, manufacturing methods, and proposed labeling of a medical device. 21 U.S.C. § 36Oe(c)(1)(A)-(G). The average time required for review is approximately 1200 hours. Fry v. Allergan Medical Optics, et al., 695 A.2d 511, 513 (R.I. 1997).

> ...no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA implemented a regulation interpreting this preemption clause, which a majority of the Supreme Court in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2256 (1996) found to be entitled to substantial weight:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by [the act's preemption clause] because they are not 'requirements applicable to a device' within the meaning of [the preemption clause]. The following are examples of State or local requirements that are not regarded as preempted by [the preemption clause]:
> (1) [The preemption clause] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or unfair trade

> practices in which the requirements are not limited to devices.
> (2) [The preemption clause] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

21 C.F.R. § 808.1(d).

In Stamps v. Collagen Corp., 984 F.2d 1416 (5th Cir. 1993), the Fifth Circuit held that the MDA preempted state law claims for defective design, inadequate warnings, and negligent failure to warn with respect to collagen implants which had undergone PMA review. The court found that the FDA scrutinizes the labeling, design, and manufacturing of a product during the PMA process, and that the plain language of the MDA preempts state law tort suits which would impose requirements different from those imposed by the FDA.

In 1996, the Supreme Court decided Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996), and shed some light on the preemptive effect of the MDA. The Court held that state law claims against Medtronic for an allegedly defective pacemaker were not preempted by the MDA. Importantly, the pacemaker at issue in that case, unlike the one currently before this Court, had not undergone full PMA review. The pacemaker in Lohr was deemed substantially equivalent to a pacemaker already on the market when the MDA was enacted, so it was approved by the FDA under the far less rigorous § 510k exception.

The Lohr decision settled some issues. At least five Justices agreed that state law tort actions are "requirements" which the MDA can potentially preempt. 116 S.Ct. at 2259, 2262. The Court was unanimous that because the § 510k procedure says nothing about a product's safety, the FDA's § 510k approval of a product does not preempt a state law claim

that the product is defectively designed. Id. at 2254, 2263-64. A majority of the Court also held that FDA Good Manufacturing Practices and labeling requirements are not sufficiently specific and do not relate only to medical devices, so they do not preempt state law claims for manufacturing defects and failure to warn. Id. at 2258. Finally, the Court was unanimous that claims for products manufactured in *violation* of FDA requirements are not preempted. Id. at 2255, 2264.

The Lohr case does not address the situation before this Court in which the allegedly defective product received the more rigorous PMA scrutiny from the FDA. This Court finds that the Lohr case is distinguishable, because as a majority of the Court stated: "[t]he 510(k) process is focused on *equivalence*, not safety." 116 S.Ct. at 2254. The PMA process is focused on safety -- PMA means that the FDA has received "resonable assurance" that a device is both safe and effective. 21 U.S.C. § 360c(a)(1)(C). Although a count of the positions of Supreme Court Justices from the concurrence and dissent is not binding, this Court also notes that at least five Justices would likely support the preemption of state law concerning a device which had gone through the PMA process.

Nearly all courts which have considered the issue in the wake of Lohr have agreed with this position. See Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997) (state law products liability and misrepresentation claims concerning an allegedly defective pacemaker were preempted by MDA where pacemaker had received investigational device exemption {IDE), requiring a process similar but not identical to PMA); Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) (strict liability and breach of implied warranty claims concerning prosthetic hip which had received IDE were preempted, but claim that the manufacturer did not follow approved FDA procedures was not preempted); Berish v.

Richards Medical Co., 937 F. Supp. 181 (N.D.N.Y. 1996) (same); Arthur Fry v. Allergan Medical Optics, et al., 695 A.2d 511 (R.I. 1997} (claims for allegedly defective intraocular lens implant which had undergone PMA review were preempted); Green v. Dolsky, 685 A.2d 110 (Pa. 1996) (same holding for collagen implants); but see Rodriguez-Suris v. Montesinos, 935 F. Supp. 71, 75 n.3 (D. Puerto Rico 1996).

The Court therefore follows pre-Lohr Fifth Circuit precedent, the implication from Lohr, and the vast majority of cases decided since Lohr, and holds that § 360k of the MDA preempts some state claims brought against the manufacturers of products which have obtained PMA from the FDA. The remaining question is which claims are preempted.

II. PLAINTIFF'S CAUSE OF ACTION

At a hearing on August 5, 1997, Plaintiff represented to the Court that she had three causes of action: (1) a claim that the pacemaker lead was unreasonably dangerous as designed; (2) a claim that the pacemaker lead was unreasonably dangerous as manufactured; and (3) a claim that Medtronic breached an implied warranty that the lead was safe and fit for the purposes for which it was intended. The Court notes that Plaintiff's original complaint makes several other claims, including a claim for negligent failure to warn.

The Court finds that any claim challenging the design of the Model 4004 ventricular lead is preempted by § 360k and the pre-market approval of the lead by the FDA. The rigorous PMA process certainly constitutes a specific federal requirement relating to the design of the lead, and allowing a state common law suit challenging that design to go forward could impose additional and even inconsistent requirements.

The Court also finds that any claim in which the Plaintiff challenges the manufacturing processes which were approved by the FDA is preempted. Although the Court notes that the Lohr Court held that general Good Manufacturing Practices were not sufficiently specific to preempt manufacturing defect claims, here the FDA approved specific manufacturing plans as part of the PMA process. Similarly, the Court finds that any claim in which the Plaintiff challenges the adequacy of the warnings which were approved by the FDA is preempted. Although general labeling requirements are not enough to create federal preemption, here the FDA specifically approved the packaging, labels, and supplemental materials which were to accompany the lead. In fact, any change in the manufacturing or labeling that could effect the Model 4004 lead's safety and effectiveness would have required prior FDA approval. 21 U.S.C. § 36Oe(e)(1)(B),(E); 21 C.F.R. § 814.39(a).

The claims described above are preempted whether they are couched in terms of products liability, breach of warranty, negligence, gross negligence, or state law deceptive trade practices. This does not mean that all potential claims are preempted. For example, Plaintiff could claim that the manufacturing processes, specifications, or materials actually used by Medtronic were not the same as those that were approved by the FDA. The Court therefore grants the parties 120 days to conduct discovery in order to determine whether Plaintiff wishes to press any non-preempted claims.

CONCLUSION

For these reasons the Court grants in part and denies in part Defendant's motion for summary judgment. The parties are granted 120 days to conduct further discovery in order to determine whether any viable claims remain.

ORDERED this 8 day of August, 1997.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

LIRBA SALAZAR

V.

MEDTRONIC, INC.

CA. NO. C-96-425

ENTERED August 27, 1999

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR RECONSIDERATION

This is a products liability suit. Jurisdiction is proper in the Court because there is complete diversity of the parties, 28 U.S.C. 1332.

Plaintiff claims she was injured when a Model 4004M ventricular lead in a pacemaker manufactured by defendant failed after implantation. Defendant moved for summary judgment on the grounds that plaintiff's claims are preempted by § 360k of the Mdeical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. § 360k. The Court granted in part and denied in part defendant's motion because the device in question received full pre-market approval (PMA) from the FDA and, therefore, § 360k preempted some, but not

all, of plaintiff's potential claims. Specifically, the Court noted that "[p]laintiff could claim that the manufacturing processes, specifications, or materials actually used by [defendant] were not the same as those approved by the FDA," and granted additional time to conduct discovery and determine whether non-preempted claims existed. Plaintiff has not offered evidence that the processes, specifications, or materials defendant used in manufacturing the Model 4004M ventricular leads differed from the approved processes, specification, or materials. Accordingly, the Court grants defendant's renewed motion for summary judgment on this remaining issue.

In her Memorandum Brief, plaintiff suggests the Court reconsider and find her claims are not preempted by the MDA, set aside its order granting partial summary judgment, and schedule this case for trial on all claims. Plaintiff argues the Court should withdraw its previous order granting defendant's motion for summary judgment because of the United States Court of Appeals for the Eleventh Circuit's recent decision in *Goodlin v. Medtronic Inc.*, 167 F.3d 367 (11th Cir. 1999). The Eleventh Circuit found 21 U.S.C. § 360(k) does not preempt state law claims based on the failure of Medtronic Model 4004M ventricular leads. *Goodlin v. Medtronic Inc.*, 167 F.3d 1367, 1377 (11th Cir. 1999). In *Goodlin*, the Eleventh Circuit's decision was based on its finding that the PMA process did not impose specific federal requirements. Id. at 1373-1377. The Fifth Circuit has held to the contrary. *See Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-23 (5th Cir. 1993), *cert. denied*, 114 S.Ct. 86 (1993). The Seventh Circuit has also concluded that the PMA process imposes specific federal requirements. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997), *cert denied*, 118 S.Ct. 1300 (1998). The Court follows the Fifth Circuit's conclusion in *Stamps* and the Seventh Circuit's conclusion in *Mitchell*. Accordingly, the Court denies plaintiff's motion for reconsideration.

ORDERED this 25 day of August, 1999.

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H. W. HEAD, JR.
UNITED STATES DISTRICT JUDGE

Supreme Court, U.S.
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OFFICE OF THE CLERK

(2)

No. 01-441

In the Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state-law claims challenging the design of Medtronic's Model 4004 and Model 4004M pacemaker leads, the manufacturing processes used to make the devices, and the devices' labeling, where those devices were granted pre-market approval by the Food and Drug Administration ("FDA"), and where each of petitioners' claims would impose requirements relating to the safety or effectiveness of the devices that would be "different from, or in addition to" the federal requirements embodied in the FDA's pre-market approval of those devices.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

The petition for certiorari in this case is virtually identical to that filed in *Kemp* v. *Medtronic, Inc.*, No. 00-1766, which this Court denied on October 1, 2001. See 122 S. Ct. 48. There is no reason for a different disposition of the present petition. The petitioners in both cases assert that the Court should grant review because *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has caused confusion in the lower courts. However, like *Kemp*, the instant case — which was decided by the Fifth Circuit consistently with both *Lohr* and the holdings of the great majority of lower courts — is not the vehicle in which to attempt to clarify the scope of preemption under Section 360k of the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

While there may be some inconsistency in lower courts' interpretations of *Lohr*, the conflict in authority is not nearly as "deep" or "profound" as petitioners contend. The overwhelming weight of authority supports the Fifth Circuit's view that the FDA's rigorous pre-market approval (PMA) process, which is vastly different from the "substantial equivalence" review given the device at issue in *Lohr*, yields federal requirements that are specific to the device and preemptive under the *Lohr* framework. Furthermore, this Court's recent decision in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may very well influence how lower courts analyze and ultimately determine the preemptive effect of the PMA process. Giving the lower courts the opportunity to address these issues in light of *Buckman* could preclude any need for this Court's intervention.

STATEMENT

As in *Kemp*, the petition provides almost no information about either the claims that petitioners actually raised below or about the lengthy and comprehensive PMA process to

which the specific medical devices at issue were subjected. After briefly outlining the background legal structure applicable to preemption under the MDA, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA — in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class III" devices (those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "pre-market notification" under the "510(k)" process as the

"substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-493.

The *Lohr* Court explicitly differentiated 510(k) approval of a device from the PMA process, at issue in this case:

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review, *id.* at 479, and never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one needed to engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that were arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process — which focuses on "entirely ge-

neric concerns about device regulation generally" (*id.* at 501), that is, on the competitive disadvantage that would be caused if new items the substantial equivalent of a pre-existing device were not easily marketable — did not pre-empt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device, and thus plaintiffs would not have been injured. The Court — noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (121 S. Ct. at 1020) — found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 1019.

B. The Extensive Regulatory History Of The Model 4004 and 4004M Devices.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 121 S. Ct. at 1015; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. The path to approval of the Models 4004 and 4004M pacemaker leads at issue in this case demonstrates the thoroughness of that review.[1] When the FDA approved Medtronic's

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[1] Petitioner Martin received a Model 4004 pacemaker lead, while Petitioner Salazar received a Model 4004M lead. As explained further below (at 9), the Model 4004 was the immediate predecessor to the Model 4004M; the only difference between the two is a

application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of the predecessor, Model 4003 lead. Before the FDA determined, in approving the Model 4004M and 4004 PMAs, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that those leads were safe and effective for their intended use, the devices and their direct predecessor models (in particular, the Model 4003) were rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004 and Model 4004M pacemaker leads.[2]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.

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minor change to a connector pin. Both devices were subjected to similar agency review — the successor 4004M lead was approved through a "PMA supplement" to the 4004 lead approval. See page 9-10, *infra*. Petitioners have never contended that there is any significant difference between the 4004 and 4004M leads; in fact, in their brief to the Fifth Circuit they incorrectly asserted that both petitioners received Model 4004M leads, while in this Court they incorrectly assert (at Pet. 10) that both petitioners received Model 4004 leads.

[2] This description is based on the affidavit of Charles H. Swanson at Salazar R.1520-40, and the affidavit of Charles H. Swanson at J.A. 98-119 in *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001); see also *id.* at 219; Salazar R. 888-894; Martin R. 805-811, 1661-1679.

- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.

- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.

- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request, and required it to continue the investigation under the existing limits.

- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.

- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983 required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing, and (2) "the fate of the implanted lead, in terms of potential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.

- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who

had particular experience recognizing potential complications from the leads.

- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.
- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.
- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.
- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.
- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.
- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition,

Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.

- In April 1986 — 30 months after Medtronic first filed a PMA request — the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.

- On May 23, 1986, the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that the device was safe and effective for its intended use, and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.

- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.

- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new

product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.

- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had only been done on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.

- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA for the Model 4004M lead on March 28, 1990, subject to the same condi-

tions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004 and 4004M leads lasted *eight years* — from March 1982 to March 1990 — and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M lead, the Model 4004 lead, and the predecessor models to these leads.

C. Petitioners' Cases In The Lower Courts.

Lirba Salazar allegedly was injured when her Model 4004M lead malfunctioned. See Pet. App. 37a. Salazar filed a product liability action against Medtronic in the United States District Court for the Southern District of Texas on August 22, 1996.

Billye Jean Martin allegedly was injured when her Model 4004 lead malfunctioned. See Pet. App. 24a. Martin originally filed a product liability suit against Medtronic in Texas state court on August 21, 1996. Medtronic removed the case to the United States District Court for the Southern District of Texas, the same court in which Salazar's suit was pending. *Id.* at 23a.[3]

Although the complaints in both cases asserted various negligence, strict product liability and Texas Deceptive Trade Practices Act claims, including claims for negligent failure to warn, petitioners ultimately represented to the district court that they actually were bringing the following causes of ac-

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[3] Martin and Salazar were represented by the same counsel, and both cases were before the same district court judge at the same time. Although the cases were not formally consolidated in the district court, the procedural history of and the briefing in the two cases are virtually identical. The two cases were formally consolidated on appeal.

tion: (1) claims that the leads were unreasonably dangerous as designed and manufactured; and (2) claims that Medtronic breach an implied warranty that the leads were fit and safe for their intended purposes. Pet. App. 30a-31a, 43a.

1. The District Court Proceedings.

On August 8, 1997, the district court granted in part Medtronic's motions for summary judgment in each case. The court did not find, as petitioners assert (at Pet. 11), that "*all* of petitioners' state-law claims are preempted" (emphasis added); rather, the court held that the MDA preemption provision, 21 U.S.C. § 360k(a), preempted those claims challenging the designs approved by the FDA, the manufacturing processes approved by the FDA, or the adequacy of the warnings approved by the FDA. Pet. App. 31a, 43a-44a. The district court found that such claims were preempted regardless of the theory under which they were brought. *Id.* at 31a, 44a. The court was careful to point out, however, that not all possible tort claims would be preempted, giving as an example a claim that Medtronic deviated from the manufacturing processes, specifications, or materials approved by the FDA. See *ibid.* The court gave petitioners 120 days in which to conduct discovery and decide whether to bring any non-preempted claims. Pet. App. 32a, 44a.

Petitioners chose not to pursue these non-preempted claims. Almost ten months later, Medtronic filed a second motion for summary judgment in each case, accompanied by affidavit testimony and documentary evidence establishing that Medtronic, in manufacturing the leads, had not deviated from the design, processes, specifications, or materials approved by the FDA. Petitioners did not offer any controverting evidence — neither asserting that Medtronic had intentionally altered the design or manufacturing processes of the devices without FDA approval nor asserting that petitioners' specific devices suffered from an unintentional manufacturing defect — nor did they assert any other claims they con-

tended were not preempted. Pet. App. 34a, 47a. On August 27, 1999, the district court granted Medtronic summary judgment, holding that petitioners had presented no evidence to support a claim that the leads failed to comply in any way with the FDA requirements applicable to the devices, as established through the PMA process. See *ibid.*

2. The Court Of Appeals Decision.

On appeal to the Fifth Circuit, petitioners accepted the district court's holding that in manufacturing the challenged leads Medtronic had not deviated from the processes, specifications, or materials approved by the FDA. Thus, as the Fifth Circuit observed, the only state-law claims at issue were those challenging the safety and effectiveness of the design, manufacturing processes, warnings, and labeling of the leads, as approved by the FDA. Pet. App. 3a, 21a-22a; see also Pet. 12 ("Petitioners did not pursue" any claim that Medtronic "did not use the PMA processes actually approved by the FDA.").[4]

The court of appeals began by recognizing that it was not writing on a blank slate. The Fifth Circuit had previously held, in *Stamps* v. *Collagen Corp.*, 984 F.2d 1416 (1993), "that similar state product liability claims were preempted" (Pet. App. 2a) when the device at issue had undergone the FDA's "rigorous pre-market approval procedure" (*ibid.*). To determine whether *Stamps* remained binding precedent following *Lohr*, and thus dispositive of the appeal, the court painstakingly analyzed the opinions in *Lohr*.

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[4] In their opening brief to the Fifth Circuit (at 30-32), petitioners argued that their failure to warn claims based on information acquired after the product was approved by the FDA would not be preempted. As petitioners now acknowledge (Pet. 12), however, evidence to support such a claim was never presented.

Stamps held that common law tort suits impose state "requirements" for the purposes of MDA preemption. *Stamps*, 984 F.2d at 1423. The Fifth Circuit in this case found that a majority of the Justices in *Lohr* "clearly agreed with this proposition." Pet. App. 13a. *Stamps* also held that common law duties would be preempted "to the extent that they relate[d] to safety, effectiveness, or other MDA requirements." *Stamps*, 984 F.2d at 1424 . After carefully considering the *Lohr* majority opinion and Justice Breyer's concurrence, the Fifth Circuit concluded that *Lohr* had not overruled the *Stamps* holding "that common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law." Pet. App. 18a. The Fifth Circuit further found that, "[g]iven the difference between the intensive PMA review and the minimal requirements under the Section 510(k) process," *Lohr* had not called into question *Stamps*' holding that "common law duties can impose requirements different from or in addition to the PMA process." *Ibid.*

Finally, the Fifth Circuit turned to the holding in *Stamps* that "the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption." See Pet. App. 19a. Based on a detailed analysis of *Lohr*, the court of appeals determined that the FDA's express approval of the proposed design, labeling, and manufacturing of the Model 4004M lead — coupled with the statutory prohibition on modifying those requirements without FDA approval — established specific federal requirements applicable to the device under the MDA. See *id.* at 19a-21a.[5]

Recognizing that *Lohr* had held that "Congress intended the preemption of some state-law causes of action" (Pet.

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[5] As discussed above (at 5 n.1), petitioners did not differentiate between the Model 4004 and Model 4004M leads in the court of appeals.

App. 20a), thereby triggering preemption under 21 U.S.C. § 360k(a)(1), the Fifth Circuit then turned to the specifics of petitioners' claims. As the court of appeals noted, petitioners alleged that "Medtronic breached state law duties by designing a pacemaker lead that contained certain materials, by labeling the lead with certain warnings, and by manufacturing the lead in a certain way." Pet. App. 21a. The court concluded that these claims were expressly preempted because they "relate[d] to areas specifically covered in the PMA process, and seek to impose requirements that are different from and, indeed, conflict with the PMA process." *Ibid.* Like the district court, the court of appeals found that only those claims challenging the design, manufacturing processes, and labeling *approved by the FDA during the PMA process* were preempted, but that because petitioners did not pursue any claim based on failure to abide by those FDA-approved processes, all claims presented to the court fell within this preempted category. See *id.* at 21a-22a.

REASONS FOR DENYING THE PETITION

Petitioners assert that review is necessary here because of the disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the petition, as it did only last month to the virtually identical petition filed in *Kemp*. In light of this Court's recent decision in *Buckman*, the Court should allow the lower courts time to revisit preemption issues under the MDA (see Part I.A). Moreover, as we explain in Part I.B, the lower courts are in significantly less disarray than petitioners suggest. In any event, given the extensive FDA scrutiny of the Model 4004 and Model 4004M pacemaker leads, the Fifth Circuit's decision is plainly correct (see Part II).

I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR.*

A. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption Of State Law Tort Actions.

While the *Buckman* Court focused on implied preemption under the MDA, this Court should nonetheless allow the lower courts time to consider the implications of *Buckman* before expending further effort on issues that the lower courts may resolve themselves in light of that case.

At least three aspects of the *Buckman* decision may assist courts in determining the preemptive scope of the PMA process. First, the Court in *Buckman* described how "thorough" the PMA process is as compared to the 510(k) process found non-preemptive in *Lohr*. See 121 S. Ct. at 1015. Second, the Court clarified that while *Lohr* "can be read to allow *certain* state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 1020 (emphasis added). Finally, the Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought to achieve under the MDA scheme and stressed how allowing certain state law claims would disrupt that balance. *Id.* at 1017.

All three aspects of *Buckman* may well influence lower courts' views about the preemptive effect of the PMA process. For example, the first reinforces the accuracy of the Fifth Circuit's holding that *Lohr*'s analysis of the preemptive scope of the 510(k) process is not applicable to the PMA process. Those few courts that have found otherwise may choose to reconsider those holdings in light of *Buckman*. Indeed, the Fifth Circuit here cited *Buckman* in contrasting the 510(k) approval process with PMA review. Second, this

Court acknowledged that at least some state law claims must be preempted by the MDA; to the extent lower courts had found otherwise those courts may now conclude that they were incorrect. If, as *Buckman* held, not all state law claims that *parallel* federal requirements may proceed, 121 S. Ct. at 1020, *a fortiori* at least some of those that *differ* from federal requirement should likewise be preempted. Finally, it is hard to see how the "delicate balance" cut by the MDA would not be disrupted by allowing states to impose conflicting requirements on devices approved by the FDA pursuant to the arduous PMA process. As the dissenting judge stressed in *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), allowing state law failure-to-warn claims might impose "conflicting labeling requirements in various states" (*id.* at 968) that differed from the FDA's "unambiguous conclusion about how * * * competing considerations should be resolved" (*id.* at 967, quoting *Lohr*, 518 U.S. at 501).

The Eighth Circuit granted rehearing en banc in *Brooks*, where the majority had found failure-to-warn claims not to be preempted, the day after this Court decided *Buckman*. See 246 F.3d 1149. Just as that court now is reconsidering whether state law claims against manufacturers of devices approved through the PMA process are preempted, a decision it will make with *Buckman* informing its consideration, so too other courts may decide to revisit preemption in the PMA context. Thus, rather than granting review on an issue that may never require this Court's attention, this Court should deny the petition and allow further development in the lower courts.

B. While There Is Some Inconsistency In The Lower Courts, It Is Far More Limited Than Petitioners Assert.

Petitioners make a great deal about the "deep post-*Lohr* split in authority" — as did petitioners in *Kemp* — asserting

that there is a conflict "in two important and related respects." Pet. 14. Their first issue, however — "whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims" (*ibid.*) — is in fact nothing but a confused summary of one aspect of their second issue. That second issue in turn has two parts; petitioners assert that there are conflicts both on whether the PMA process imposes specific, federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. While a few courts have misinterpreted *Lohr* on both what federal requirements may be preemptive and on whether state common law claims may be preempted, the great weight of authority — and all recent authority — favors the Fifth Circuit's position on both issues.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to the device are preemptive under the MDA. See 518 U.S. at 500-501; Pet. App. 9a.[6] Based on this Court's discussion of the "rigorous" nature of the PMA process, and the Court's comparison between 510(k)-process requirements (which the Court found to be

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[6] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 22-24, *infra*.

"important but entirely generic concerns") and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements"; see *Lohr*, 518 U.S. at 501), the vast majority of courts have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 19a-20a; *Brooks*, 236 F.3d at 963-964, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Kemp*, 231 F.3d at 226-27; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to the decisions of the Fifth, Sixth, Seventh, and Eighth Circuits, petitioners can identify (at Pet. 14, 16) only one federal court of appeals and one state supreme courts that did not find PMA approval to be preemptive — *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while inconsistent with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found parts of the requirements imposed through the PMA process not to be "specific" (167 F.3d at 1376), while acknowledging that other aspects *were* specific (*ibid.*). The FDA's "conditions of approval," barring modification of a device without FDA consent, were specific federal requirements, the court acknowledged, but it found that these were not "'applicable under [the MDA] to the device.'" *Ibid.* (quoting 21 U.S.C. § 360k(a)(1)). This latter holding is not only inconsistent with the former holding but also contrary to *Lohr*, which focused on whether federal requirements were specific or general requirements, not whether they were applicable exclu-

sively to the specific device. See 518 U.S. at 500 ("federal requirements must be 'applicable to the device' in question" under FDA regulations). In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that all aspects of the PMA process were not specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: first, the court held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*) — a statement that, while perhaps true for the device at issue in *Weiland*, certainly was not true in this case, where the FDA repeatedly required modifications of the product or its labeling (see pages 6-9, *supra*); second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, this decision is plainly incorrect.[7]

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[7] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 16 n.3), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), while the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state

2. On the state side of the *Lohr* preemption equation, petitioners assert that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[8] a decision that is plainly correct under *Lohr* (see pages 25-26, *infra*). Only one federal court of appeals or state court of last resort (*cf.* S. Ct. R. 10) has relied on a contrary finding to limit the preemptive scope of the MDA — the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997). That case is one of the earliest appellate decisions to interpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.[9]

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requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

[8] See, *e.g.*, Pet. App. 14a-18a; *Kemp*, 213 F.3d at 224; *Brooks*, 236 F.3d at 963, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[9] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements — despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state law duty would "have the effect of establishing a substantive requirement of a specific device" — even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See page 25, *infra*.[10] This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In four years, there has been no movement by any other court toward the erroneous Oja analysis, and there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*, in light of the overwhelming weight of authority of other courts of appeals and the opinion of the FDA (see page 27 n.13, *infra*) that such state law claims may be preempted.

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[10] Petitioners' assertion that the Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822. As discussed above (at page 19 n.7), the court also focused on the significant differences between the PMA process and the IDE process.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur there must be a federal requirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Fifth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific).

The decision below makes eminent sense. The PMA process imposes a host of specific federal "requirement[s]" on devices such as the Model 4004M lead.[11] We described

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[11] Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360(e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2),

above (at pages 5-10) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plans to distribute the 4004 and 4004M leads. During that process, "[t]he design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process." Pet. App. 21a; see also *Kemp*, 231 F.3d at 226-27 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913). And most important, approval under the PMA entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477, citing 21 U.S.C. § 360e(d)(2). The determination that a product is safe and effective, weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (21 U.S.C. § 360c(a)(2)(C)), after a process characterized by the Supreme Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 121 S. Ct. at 1018), is of necessity the determination that the details of that device are an appropriate compromise that should not be modified by state law.

360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f)), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), but that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, *the counterpart FDA requirement is established on the date the device can not lawfully be marketed without application for premarket approval.* * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue *by expressly exempting it* (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary were the PMA process not a requirement otherwise preemptive of the state law.

2. The Fifth Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device differed from the one required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes pre-empt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part). The court below, like *Lohr*, found that state law claims that impose a duty identical to federal requirements would not be preempted. See Pet. App. 21a-22a. But where a state law tort action is based on a requirement that is *not* identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement.

Here, the PMA imposed a specific requirement on Medtronic to make its Model 4004 and Model 4004M leads using the specific design approved, which included using a particular material for the leads' insulation and using the manufacturing processes Medtronic described in its PMA application. By contrast, Texas law requires a plaintiff asserting a design defect to demonstrate an "alternative design," TEX. CIV. PRAC. & REM. CODE § 82.005 (Vernon 1997), see also *Uniroyal Goodrich Tire Co.* v. *Martinez*, 977 S.W.2d 328, 335 & nn. 3, 4 (Tex. 1998) — a design necessarily lacking FDA approval. Moreover, the PMA required Medtronic to use the labeling the FDA approved. Were a jury to impose liability on Medtronic under Texas law for not making the Model 4004M lead with different insulation material, for example,

or for not using different manufacturing processes, that jury would plainly be imposing a different, additional requirement on the lead[12] — and an additional requirement that could itself differ from requirements imposed in other states.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review

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[12] For example, design defect cases in Texas are governed by statutory and common law rules requiring the jury to find that the product as designed is unreasonably dangerous, using a definition that requires balancing risk and utility. 3 COMM. ON PATTERN JURY CHARGES, STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES PJC 71.4B (1998). This is directly parallel to review during the PMA process. Under FDA regulations, the panel reviewing a device for PMA also must weigh "the probable benefit to health from the use of the device" against any risk of injury or illness from its use. 21 C.F.R. § 860.7(b)(3). In order for a panel to conclude that there is the statutorily-required "reasonable assurance that a device is safe," there must be "valid scientific evidence[] that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks." *Id.* § 860.7(d)(1). Thus, were a Texas jury to find the Model 4004 or Model 4004M lead to have a design defect, the jury would have to find that its risks outweigh its benefits, a finding irreconcilable with the finding of the FDA in granting PMA.

and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.[13]

* * * * *

In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of *Buckman* and through further litigation in the lower courts. Petitioners provide no good explanation for why the Court, having just declined to review this very issue in *Kemp*, should grant review in this case, or why the issue deserves the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

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[13] Petitioners purport (at Pet. 20 & n.5) to present evidence of the United States' view on the questions presented herein. The positions taken three years ago in the Solicitor General's brief in *Smith Industries Medical Systems, Inc.* v. *Kernats*, 522 U.S. 1044 (1998) (mem.), were based on the FDA's then-pending proposed rulemaking procedure. See United States Brief in *Kernats*, at 14, 19-20. The FDA has since withdrawn that proposed rule, see Pet. 20-21 n.5, and there is no evidence that those positions reflect the current views of the agency. In any event, petitioners' reliance on the views of the United States is selective. The Solicitor General more recently took the position that "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts * * *." United States Brief in *Buckman*, at 12 n.1.

Respectfully submitted.

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No. 01-441

IN THE

Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

Respondent Medtronic, Inc. does not contest that the petition presents an important federal preemption question under the Medical Device Amendments ("MDA") that has divided the federal and state appellate courts. The split in authority is illustrated most pointedly by decisions of the federal courts of appeal, including the decision below, that have arrived at diametrically opposed legal conclusions on the question presented in cases involving the same defendant and the same medical device. *See* Pet. 3-4. In opposition, respondent asserts, first, that review should be denied because review was denied in *Kemp v. Medtronic, Inc.*, No. 00-1766, a case that it asserts is "virtually identical" to the present case. Opp. 1, 14; *see* Opp. 27. Respondent also claims that the split in authority, although genuine, does not warrant this Court's attention. Medtronic's arguments are incorrect, and the Court should grant the petition.

I. THE DENIAL OF CERTIORARI IN *KEMP* IS IRRELEVANT.

Respondent now claims that *Kemp* presented the same question as that presented here, both beginning and ending its opposition on that theme. Opp. 1, 27. However, that is not what respondent said in its *Kemp* opposition. Indeed, respondent began that opposition by restating the question presented and then asserting, "[h]owever, as we explain in this brief, that question is not in fact presented by this case." Brief for the Respondent in Opposition in *Kemp v. Medtronic, Inc.*, No. 00-1766, at (I) (filed July 23, 2001). Respondent then argued, as the *principal* basis for denying review, that the Kemps were requesting "nothing but an improper advisory opinion" because they had "raised only three claims in the Sixth Circuit...[,] *none of which is before this Court.*" *Id.* at 15 (emphasis in original); *see also id.* at 15-16 (same).

By contrast, here, although respondent claims that "like *Kemp*," this case "is not the vehicle to clarify" the question presented, Opp. 1, respondent does not — because it cannot — claim that the MDA preemption question posed by petitioners is not squarely presented. Thus, quite apart from the ordinary rule that a denial of certiorari carries no weight, if this Court denied review in *Kemp* on the main basis urged by respondent, the Court's disposition in *Kemp* is irrelevant.

Unable to argue directly that the preemption issue is not presented, respondent seeks to obscure the legal issue with a particularly extended discussion of facts and procedural history that quibbles with the petition on some incidental details. Only one of respondent's assertions requires correction at this juncture because of its potential for confusion: respondent's statement that the district court did not hold all of petitioners' claims preempted. Opp. 11. An examination of the district court's orders shows clearly that it did. Pet. App. 23a-48a. That the district court recognized that some claims *not* advanced by petitioners would not be preempted is beside the point. *See* Pet. 11-12.

II. THE QUESTION PRESENTED INVOLVES A DEEP AND UNRESOLVED SPLIT IN AUTHORITY THAT CALLS FOR RESOLUTION BY THE COURT AT THIS TIME.

Respondent contends that the Court should deny review because the decision in *Buckman Company v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may alter the legal terrain and because the split in authority among the lower courts is not as serious as petitioners maintain. Neither contention is persuasive.

A. Respondent asserts that the Court should defer review because *Buckman* "may assist [lower] courts" in resolving the question presented. Opp. 15. Respondent ignores

the key reason why *Buckman* is irrelevant here: In holding that a fraud-on-the-FDA claim is impliedly preempted by federal law, *Buckman* explicitly distinguished claims, such as those at issue here, that "rely[ ] on traditional state tort law which had predated the federal [MDA] enactments in question." 121 S. Ct. at 1020.

Beyond that basic omission, respondent makes three points related to *Buckman*, none of which has merit. First, it notes that *Buckman* said that the PMA process is "thorough" compared to the 510(k) process at issue in *Lohr*. Opp. 15. Actually, *Buckman* mentioned that point only in passing, 121 S. Ct. at 1015, as the device at issue there was not a PMA device. *Id.* at 1015-16.

Second, respondent asserts that *Buckman* clarified that, under *Lohr*, only "certain" state-law causes of action that parallel federal requirements may go forward. Opp. 15. That supposed clarification also has nothing to do with this case. Petitioners certainly maintain that their claims are compatible with, *i.e.*, not "different from, or in addition to[,]" federal law — for instance, their manufacturing-defect claim is fully consistent with the FDA's good manufacturing practices rules, *see* 20 C.F.R. Part 820. However, their causes of action are based exclusively on general state-law claims regarding manufacturing and design defect and failure to warn, Pet. 11, not on claims of negligence *per se* for violations of federal rules. Equally important, the principal cases reflecting the deep divide among the lower courts also involve general state-law claims. *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 (11th Cir. 1999); *Oja v. Howmedica*, 111 F.3d 782, 784-85 (10th Cir. 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151 (Ill. 1999); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 906 (7th Cir. 1997). Thus, none of those precedents could possibly be affected by *Buckman*'s comment regarding state-law causes of action that parallel federal requirements.

Third, respondent relies on *Buckman*'s statement that a state-law fraud-on-the-FDA claim would disrupt the balance that Congress was trying to achieve under the MDA. Opp. 15-16. That implied preemption rationale does not relate to the question presented here — whether 21 U.S.C. 360k(a) expressly preempts the Kemps' claims based on "traditional state tort law." *Buckman*, 121 S. Ct. at 1020. In this regard, it is important to consider what was at issue in *Buckman*. The theory of the case was unrelated to whether the product was properly designed or manufactured or accompanied by appropriate warnings; rather, it was premised entirely on the notion that the product would not have been marketed if not for the defendant consultant's fraudulent submissions to the FDA. Thus, the Court's concern about the balance struck by Congress related to the potential for interference with the internal workings of the FDA, *id.*, not with the independent tortious conduct of device manufacturers in their interactions with device users and physicians, which is the basis for petitioners' claims. Moreover, the Court's ruling was based solely on *implied preemption* principles and did not even discuss whether a fraud-on-the-FDA claim, let alone the "traditional state tort law" claims at issue here, is preempted by the MDA's express preemption provision, 21 U.S.C. 360k(a). Indeed, *Buckman*'s only reference to section 360k(a) is in a footnote stating that the Court would *not* consider the question whether a fraud-on-the-FDA claim is expressly preempted. 121 S. Ct. at 1017 n.2. In sum, the fraud-on-the-FDA ruling in *Buckman* has no bearing on the question presented here.

Respondent's argument is necessarily based on the premise that post-*Buckman* express preemption cases involving PMA devices will be influenced by *Buckman*. That premise is wrong. *Buckman* has played no role in PMA cases finding preemption, such as *Kemp* and the decision below, or in cases finding no preemption. Indeed, the most recent federal court

decision to address this issue followed the Eleventh Circuit's no-preemption holding in *Goodlin*, and, although it cited *Buckman* in passing, it did not find that decision relevant to, let alone dispositive of, the express preemption issue. *See Webster v. Pacesetter, Inc.* ___ F. Supp. 2d ___, 2001 WL 1359969 (D.D.C. Nov. 1, 2001).

The very few cases that have addressed whether *Buckman* alters the preemption analysis are, not surprisingly, *implied preemption* cases involving drugs (not devices), and every one of them has rejected preemption on the ground that *Buckman*'s fraud-on-the-FDA analysis does not apply to "traditional" tort claims against the product manufacturer. *See Caraker v. Sandoz Pharmaceuticals Corp.*, ___ F. Supp. 2d ___, 2001 WL 1190858, *16-*17 (S.D. Ill. Sept. 4, 2001); *Dawson v. Ciba-Geigy Corp.*, 145 F. Supp. 2d 565, 572-73 (D.N.J. 2001); *Globetti v. Sandoz Pharmaceuticals Corp.*, 2001 WL 419160, *1-*2 (N.D. Ala. Mar. 5, 2001). In sum, neither logic nor even a sliver of case authority supports respondent's argument that *Buckman* provides a basis to deny review.*

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*In this regard, respondent's reliance on *Brooks v. Howmedica, Inc.*, 226 F.3d 966 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), *see* Opp. 16, is misplaced. *Brooks* involves solely the question whether a traditional state-law failure-to-warn claim is expressly preempted by section 360k(a), and does not present design or manufacturing-defect claims like those presented here. Respondent appears to find significance in the fact that rehearing en banc was granted in *Brooks* the day after *Buckman* was decided. *See* Opp. 16. However, the timing of the *Brooks* order is obviously happenstance, unless one believes that, sensing a need to act immediately, the full complement of Eighth Circuit judges read this Court's decision, conferred, and granted the en banc petition within 24 hours.

B. Respondent's argument that the current split of authority among the federal courts of appeals and state courts of last resort is not significant, Opp. 16-21, is largely answered by the petition and we do not repeat it here. *See* Pet. 14-18. Moreover, although the continuing division among intermediate state appellate courts — the existence of which respondent does not contest — may not be an independent basis for granting certiorari under this Court's Rule 10, it does show that the division among the courts of appeals and the state courts of last resort is creating broad confusion in the judicial system that requires this Court's attention. In any event, respondent's claim of a shallow split is rhetorical, as the opposition's main thrust is not that the split is insignificant, but rather a critique of the merits of the key decisions with which respondent disagrees. Opp. 18-21. That the courts have taken differing views on the merits, however, only underscores the need for review.

Two of respondent's specific assertions warrant correction. First, respondent claims that the Kentucky Supreme Court's decision in *Niehoff v. Surgidev Corp.*, 950 S.W. 2d 816 (Ky. 1997), is inapposite because the device there went through the investigational device process, not the PMA process. Opp. 19 n.7. However, *Niehoff* held both that the investigational device process does not trigger preemption *and* that state-law tort claims based on duties of general applicability are not sufficiently specific to trigger preemption under 21 U.S.C. 360k(a). That latter holding applies with equal force to claims involving PMA devices and directly conflicts with the decision below. Respondent's assertion that *Niehoff* did not so hold, Opp. 21 n.10, is belied not only by the language of the decision itself, *see* 950 S.W. 2d at 822 ("Kentucky's strict liability case law and statutes [on which the plaintiff relied] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"), but also by the Kentucky Court of Appeals' decision in *Leslie v. Cincinnati*

Sub-zero Products, Inc., 961 S.W. 2d 799, 802-03 (Ky. App. 1998), whose understanding of *Niehoff* is identical to that of petitioners.

Second, we reiterate that, in December 1997, *before* the Eleventh Circuit's decision in *Goodlin* and the Illinois Supreme Court's decision in *Weiland*, the Solicitor General maintained that the "current division" in the courts would have called for review by this Court, except for unusual circumstances not present here. *See* Pet. 20-21 & n.5 (discussing Solicitor General's amicus brief in *Smith Industries Medical Systems v. Kernats*, No. 96-1405). Respondent's assertion that the government's position in *Kernats* was based on the pendency of a now-withdrawn proposed FDA regulation is flatly incorrect. The Solicitor General argued at length that the no-preemption decision in *Kernats* was correct. *See* Brief for the United States as Amicus Curiae in *Smith Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, at 14-18 (U.S. filed Dec. 10, 1997). That merits argument was unrelated to the proposed regulation, which was discussed at the very end of the brief only as a reason to deny review. *Id.* at 19-20. Moreover, contrary to respondent's insinuation, *see* Opp. 27 n.13, the United States specifically noted that the position it took in *Buckman* was consistent with the position it had taken in *Kernats*. *See* Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2 (U.S. filed June 7, 2000) (petition stage).

C. Even further afield is respondent's speculation that courts that have rejected preemption may revisit their no-preemption holdings, and that this Court should therefore deny review because the split in authority will go away. Absent a decision of this Court finding preemption on the question presented, there would be no lawful basis for such an about-face. Indeed, we know of no case in the Tenth Circuit (where *Oja* prevails), in the Eleventh Circuit (where *Goodlin* prevails),

in the Illinois state courts (where *Weiland* prevails), or in the Kentucky state courts (where *Niehoff* prevails) in which a defendant device manufacturer is arguing that *Buckman* or some other development requires that controlling precedent be set aside. Presumably respondent — the world's largest device manufacturer and a frequent litigant — would have brought such cases to this Court's attention if there were any. Indeed, even in state court systems where intermediate appellate courts have issued no-preemption decisions (New York, Michigan, Oregon, New Jersey, and California), *see* Pet. 16, 18, we know of no challenges to those decisions in the areas in which they control, and, again, respondent has not pointed to any.

* * *

To summarize: Petitioners' claims would not be preempted in the states comprising the Eleventh Circuit or in the state courts of Illinois, where controlling precedent holds that the PMA process does not result in specific federal requirements that are preemptive under the MDA. Nor would their claims be preempted in the Tenth Circuit or in Kentucky courts, where controlling precedent holds that state-law duties of the kind relied on by petitioners do not establish specific state-law requirements subject to preemption under the MDA.

III. RESPONDENT'S ARGUMENTS ON THE MERITS UNDERSCORE THE NEED FOR REVIEW.

The petition briefly explains why the ruling below on the merits is inconsistent with the text and purpose of the MDA and this Court's decision in *Lohr*. Pet. 20-22. Respondent, of course, argues that the ruling below is correct. Opp. 22-27. The parties' disagreements are very wide. For instance, whereas respondent argues that FDA pre-market approval transforms all specifications of the manufacturer's application

into preemptive federal requirements, Opp. 23, petitioners maintain that such specifications originate with the manufacturer, not FDA, and thus are not specific federal requirements that have preemptive force. Pet. 20. The petition and opposition reveal the parties' very different understanding of the law and of the significance of the facts concerning approval of the pacemaker leads that caused petitioners' injuries. If this Court grants review, there will be time enough to reply to respondent's merits arguments in detail. However, for present purposes, the depth of the disagreement on the merits only emphasizes the need for review. As is evident from the parties' submissions, some courts have sided with the petitioners on the merits and others with respondent. Their positions are irreconcilable and can only be resolved by this Court.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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No. 01-441

In the Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

SUPPLEMENTAL BRIEF FOR THE RESPONDENT IN OPPOSITION

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SUPPLEMENTAL BRIEF FOR THE RESPONDENT IN OPPOSITION

Pursuant to Rule 15.8 of the Rules of this Court, respondent submits this supplemental brief to draw the Court's attention to the Eighth Circuit's en banc decision in *Brooks* v. *Howmedica, Inc.*, No. 00-1188, __ F.3d __, 2001 WL 1568430 (Dec. 11, 2001), which we had noted (at Br. in Opp. 16) was pending, and which is attached as an appendix to this brief.

As we explained in our brief in opposition, there is no "'deep post-*Lohr* split in authority'" (Br. in Opp. 16, quoting Pet. 14) about the preemptive effect of the FDA's grant of premarket approval (PMA). By a 7-2 vote, the en banc Eighth Circuit has now found state law failure-to-warn claims preempted by the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, where a device had been reviewed by the FDA pursuant to the PMA process. Thus, yet another court of appeals has now explicitly held, as did the court below, that state law claims that would impose requirements "different from, or in addition to" those imposed by federal law (21 U.S.C. § 360k(a)) are preempted by the PMA process. The *Brooks* decision further undermines petitioners' claim that this case warrants the Court's review.

The *Brooks* court discussed (at App 5a-9a) the detailed and repeated review the FDA gives to a device's labeling. It noted that, under *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996),

> [t]he key question before the court is whether the specific state requirement [the plaintiff] wishes to impose on [the device] would interfere with a specific federal requirement, [which] question may also

> be phrased as whether the specific state and federal requirements conflict.

App 16a. Explaining that, under the PMA process, "[t]he FDA drafted or approved every word of the [device's] label, and any changes were subject to close FDA scrutiny" (App. 17a), the Eighth Circuit found that state law failure to warn claims were preempted under the MDA:

> The failure to warn claim asserted by [the plaintiff] would interfere or conflict with the specific federal requirements imposed during the regulation of [the device]. A jury finding of negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements.

App. 19a. See also *id.* at 23a ("Through its approval of the PMA application * * * and its continuing series of directives, the agency imposed specific federal requirements on Howmedica."). The same is true here. See Br. in Opp. 5-10.

The *Brooks* court also discussed and dismissed the two federal court of appeals decisions that petitioners rely upon to argue for review here. The Eighth Circuit distinguished *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) — as we did in our brief in opposition (at 20-21) — as a "case [that] involved approval through an investigational device exemption, a considerably less rigorous process than the full PMA" (see App. 18a, Pet. 20). It further explained (compare Br. in Opp. 18-19) that the "*Goodlin* [v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999)] court implied * * * that it would find preemption in a case involving an 'ascertainable requirement in an express FDA' order or regulation." (App. 18a (quoting *Goodlin*, 167 F.3d at 1375 (further citations omitted))).

Thus, as we noted in our brief in opposition, (at 17) "the great weight of authority — and all recent authority — favors

the Fifth Circuit's position" in the case under review, and there is no reason for the Court to grant the petition. The Eighth Circuit's *en banc* decision in *Brooks* confirms our submission that this issue does not warrant the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 2001

APPENDIX

United States Court of Appeals,
Eighth Circuit.

Carol Jean BROOKS, Plaintiff-Appellant;
ST. LUKE'S HOSPITAL, Intervenor Below,

v.

HOWMEDICA, INC., a Delaware Corporation, Division of Pfizer Hospital Products Group, Inc.; Pfizer, Inc.; Howmedica International, Ltd., Defendants-Appellees.

PRODUCT LIABILITY ADVISORY COUNCIL, INC., Amicus on Behalf of Appellees.

No. 00-1188.

Submitted: July 10, 2001.
Filed: Dec. 11, 2001.

Appeal from the United States District Court
for the District of Minnesota.

Before WOLLMAN, Chief Judge, HEANEY, McMILLIAN, BOWMAN, LOKEN, HANSEN, MORRIS SHEPPARD ARNOLD, MURPHY, and BYE, Circuit Judges.

MURPHY, Circuit J.

Carol Jean Brooks brought this action against the manufacturer of Simplex bone cement claiming damages for injury resulting from its failure to give adequate warnings about product dangers. The case was dismissed on summary judg-

ment after the district court[1] concluded that her claim was preempted by federal law, § 360k of the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. A panel of this court reversed with one judge dissenting, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001), a petition for rehearing en banc was granted, and the panel opinion was vacated. After examining the record and considering *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), we affirm the judgment of the district court.

I.

Carol Jean Brooks is a licensed practical nurse whose work as a surgical technician included mixing bone cement. Bone cement is used to bond with a bone or prosthesis in orthopedic surgeries, including joint replacements. Brooks began mixing bone cement during 1978 while she worked at St. Mary's Hospital in Duluth, Minnesota, but her principal exposure occurred after she moved to St. Luke's Hospital in Duluth in 1982. At St. Luke's she initially participated in a variety of surgeries, but in 1983 she began to assist almost exclusively in orthopedic surgeries, mixing bone cement or being present during its preparation approximately four times a week. By 1992 she was mixing bone cement or was close to the mixing process during approximately ten surgeries a week. Although Brooks is unable to identify the brand of bone cement used at St. Mary's, it is undisputed that St. Luke's used Simplex P Radiopaque bone cement (Simplex), which was manufactured and marketed by appellees (collectively Howmedica).[2]

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[1] The Honorable Michael J. Davis, United States District Judge for the District of Minnesota.

[2] At the time this action was commenced, defendants Howmedica Inc. and Howmedica International, Ltd. were wholly owned subsidiaries of defendant Pfizer, Inc. The record does not make clear which corporate entity was responsible for manufacturing or sell-

Brooks began to cough at some time in 1989 or 1990. She went to see a doctor about it in 1991 when she was told she had asthma. An occupational health physician at St. Luke's Hospital also investigated possible causes for her cough, reviewed Howmedica's Material Safety Data Sheet, and talked with a Howmedica chemist, but that investigation did not link her cough to Simplex. St. Luke's restricted her exposure to a number of chemicals after an acute asthma attack in 1992; the restriction included methyl methacrylate which is an ingredient in Simplex. Brooks was later diagnosed to have occupational asthma caused by exposure to methyl methacrylate. Brooks has been unable to work since 1995.

Brooks brought a failure to warn claim against Howmedica, alleging that it had not provided "adequate warnings and instructions" for Simplex use and that as a result, she had contracted "severe asthma and associated respiratory complications." Howmedica asserted federal preemption and also denied that the Simplex label contained inadequate warnings and instructions or that it proximately caused Brooks' injury. St. Luke's Hospital intervened, seeking compensation from Howmedica for what it had paid Brooks in workers compensation benefits, costs, interest, disbursements, and attorney fees, but it is not involved in this appeal.

II.

Starting in the early 1970's Howmedica began to market bone cement in the United States under the trade mark Simplex. Bone cement is sold in two separately packaged components: methyl methacrylate monomer which is a colorless liquid and a powder mixture containing polymethyl methacrylate, methyl methacrylate styrene copolymer, and barium sulfate. The liquid and powder are mixed together in

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ing Simplex during the time Brooks was injured, but none of the appellees has challenged its status as a defendant.

the operating room to form a pliable mass that later hardens into a cement like consistency. The mixing process releases vapors containing methyl methacrylate, which is classified as a hazardous chemical by the Occupational Safety and Health Administration.

It is undisputed that Simplex has been heavily regulated by the FDA since it entered the market when it was treated as a drug subject to the Federal Food, Drug, and Cosmetic Act of 1938 (1938 Act). The 1938 Act required Howmedica to submit a New Drug Application (NDA) before it could sell Simplex,[3] see 21 U.S.C. § 355, and the NDA is a rigorous process. The NDA process required Howmedica to disclose details of animal studies, manufacturing and quality control procedures, the identification of possible side effects, results of clinical trials, summaries of surgical cases and post operative complications, long term toxicity, and carcinogenicity studies. The process also produced reports from the investigational use of Simplex by sixty seven physicians in 1,408 hip replacements which involved 2,800 preparations of the product. All these submissions were then studied and reviewed by a panel of FDA experts. Under the 1938 Act, Simplex could not be marketed without approval by the Secretary of Health and Human Services. See 21 U.S.C. § 360(c) (premarket approval process).

The NDA included review by the FDA of the proposed design and content for all Simplex labels, including labels for a vial, a pouch, two internal boxes, an outer box, and a package insert. Howmedica employees met with members of the FDA on several occasions to discuss its application, including the product labels. The FDA reviewed every word that

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[3] Howmedica developed and submitted NDAs for two types of Simplex. The only difference between the two is that one type was detectable on x-ray and the other was not. The approval process was identical for both types, and neither side in this case differentiates between the two.

appeared on Simplex labels, and the FDA drafted the language that was used in the package insert. That package insert included the following warning:

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The vial containing the liquid component and the box with the powder both referred the user to the package insert for information regarding dosage and administration.

Simplex was approved by the FDA for use in total hip replacement surgeries in 1971. The FDA wrote "[w]e have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved."

These review requirements were affected by the 1976 Medical Device Amendments (MDA) to the 1938 Act. The MDA created three classes of medical devices, categorized by the risk to the public and the degree of regulation required. Class I devices present no unreasonable risk of illness or injury and are subject only to "general controls." 21 U.S.C. § 360c(a)(1)(A). Class II devices present greater risk than those in Class I, and they must comply with federal performance regulations called "special controls" but may be marketed without advance approval. *Id.* at § 360c(a)(1)(B). Class III devices carry "a potential unreasonable risk of illness or injury," or are used for "supporting or sustaining human life," or are seen to be "of substantial importance in preventing impairment of human health." *Id.* at § 360c(a)(1)(C). Class III devices are highly regulated and must receive pre-

market approval (PMA) from the FDA before they may be sold. *Id.* at § 360e(a).[4]

Devices such as Simplex, which had been treated as drugs prior to the amendments to the 1938 Act, were automatically reclassified by the MDA as Class III medical devices.[5] See 21 U.S.C. § 360j(l)(1). The statute provided that these devices were deemed to have PMA approval if they had gone through the NDA approval process. *Id.* at § 360j(l)(3)(A). Beginning in 1976 Simplex was accordingly treated as a Class III medical device with PMA approval.

Under both the 1938 Act and the MDA, the FDA has continuing authority and responsibility to control the content of any information or warnings Howmedica provides Simplex users. Howmedica was required to provide the FDA with regular reports of any new information learned about Simplex. See 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81, 814.84 (2000). The company was not permitted to make any changes to the product label affecting the safety or effectiveness of the device without submitting a supplemental PMA, but it could temporarily "add or strengthen" warnings during the time the FDA had any supplement under consideration. 21 C.F.R. § 814.39(a), (d) (2000).

Howmedica learned that some individuals exposed to Simplex had developed contact dermatitis, and in 1973 it requested permission from the FDA to insert the following language into its warnings: "The liquid component is a powerful lipid solvent, and may also act as a sensitizer in certain individuals." After its consideration of the request, the FDA de-

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[4] There are certain exemptions to the PMA requirement which do not apply to Simplex but are discussed in *Kemp* v. *Medtronic*, 231 F.3d 216, 221-22 (6th Cir. 2000).

[5] The FDA later reclassified bone cement from a Class III device to Class II, but that was at a time after the period during which Brooks was exposed to Simplex.

cided to direct Howmedica to revise its package insert to include this additional language:

> The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

In 1975, the FDA required bone cement manufacturers to participate in a review of the inhalation toxicity of methyl methacrylate vapors, and the Simplex warnings were reexamined. After a number of discussions, the FDA required Simplex to modify the package insert warnings concerning vapor inhalation as follows:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The FDA also directed Howmedica to send a "Dear Doctor" letter to Simplex users to warn about inhalation hazards associated with methyl methacrylate. Howmedica told the FDA it believed the letter was unnecessary because studies had shown that the concentration of methyl methacrylate vapors in operating rooms was within accepted limits, but the FDA insisted on compliance with its directive. Howmedica and the FDA then worked together to draft the letter, which directed attention to methyl methacrylate vapor inhalation studies and to the package insert warning. It also recom-

mended that hospital facilities be inspected for adequate ventilation. The final paragraph of the letter warned:

> In some sensitive individuals, exposure to MMA can cause dermatitis and other allergenic responses. If any of your operating room personnel develop such responses when using Simplex®, both prudence and good medical practice would suggest that they avoid all procedures involving use of Simplex®.

Howmedica sought to expand the uses of Simplex, and in March 1976 the FDA approved its request from the previous year to use the product in fixing pathological fractures. The FDA approved the request with the condition that Howmedica send the "Dear Doctor" letter to members of the American Academy of Orthopaedic Surgeons and to all hospital administrators and operating room supervisors at hospitals and clinics which had recently purchased Simplex. In July, Howmedica submitted a supplemental NDA to seek approval of Simplex use in elbow, wrist, ankle, shoulder, and finger joint replacement surgery. During this application process, the FDA again reviewed Simplex labels and required specific changes be made to reflect these uses. After Howmedica had made the required labeling changes, the FDA approved the application.

In 1986, Howmedica received information that soft contact lenses could be damaged by methyl methacrylate vapors and requested that additional warnings be added to Simplex labels. The FDA approved the addition of the following warning:

> It has been recommended by manufacturers of soft contact lenses that such lenses should be removed 'in the presence of noxious and irritating vapors.' Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

This addition was the final adjustment made to the Simplex warning related to occupational use during the period when Carol Brooks was exposed to the product.

III.

After discovery was complete in the district court, Howmedica moved for summary judgment. It argued that Brooks' failure to warn claim was preempted by the MDA because she sought to impose a requirement on Simplex that was different from, or in addition to, federal requirements developed through the NDA process. It also argued that any inadequacy in Simplex warnings was not the proximate cause of Brooks' injury because she admitted she had never read the product labels or package insert. Brooks argued that her claim was not preempted because the duty to warn is a general obligation applicable to all devices, and approval by the PMA or NDA does not impose specific federal requirements with preemptive effect. She also asserted at this time that Howmedica had failed to comply with general FDA labeling regulations although she had not pled such a claim in her complaint.

The district court granted Howmedica's motion and dismissed the case. After a comprehensive discussion of the relevant case law, the court concluded that even if Brooks could show that her injury had been caused by Howmedica's failure to provide her with adequate warnings and directions for use, her failure to warn claim was preempted by federal law and that she had not submitted sufficient support for any claim that Howmedica failed to comply with FDA rules or regulations.

Brooks appealed, arguing that her general common law duty to warn claim was not preempted and that the NDA and PMA are not specific federal requirements with preemptive force. She also argued that Howmedica's alleged breach of its duty under common law amounted to a violation of general FDA labeling requirements. Howmedica responded that

Simplex is deemed under the MDA to have PMA approval and that the PMA has been recognized by this court to be a federal requirement with preemptive effect, citing *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). It argued that Brooks' claim was a state requirement different from, or in addition to, the federal requirement and therefore preempted under § 360k of the MDA. Howmedica also argued that Brooks had provided no evidence that it had violated any FDA rules or regulations. Both sides contended that the Supreme Court's decision in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996), favored their respective positions.

A panel of this court reversed the dismissal of the failure to warn claim, with one judge dissenting. *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001). The majority interpreted Lohr to permit the claim to go forward, holding that the claim would not result in any actual conflict between state common law and federal requirements and was therefore not preempted. *Id.* at 964-66. The dissent pointed out that the device at issue in Lohr had been approved through a much less rigorous process than the PMA and the NDA review of Simplex, and that during the regulatory process for Simplex the FDA had considered a particular federal requirement, had concluded how competing considerations regarding that requirement should be resolved, and had imposed a specific mandate on Howmedica to that end. *Id.* at 967. The panel treated Brooks' allegation that Howmedica had not complied with FDA regulations as a common law negligence per se claim and affirmed its dismissal. *Id.* at 966-67.

Howmedica's petition for rehearing en banc was granted, and the panel opinion was vacated. The parties submitted additional briefs, and the Product Liability Advisory Council, Inc. was given permission to submit an amicus brief.[6] At

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[6] In its brief the Product Liability Advisory Council asserts that Brooks' claim is preempted under the MDA. It argues that neither

oral argument, the parties advanced substantially the same points they had made earlier, but Brooks put increased emphasis on her contention that the link between methyl methacrylate and occupational asthma had not been made until 1985. She asserts that the product warning was not changed in response to the publication in 1985 of two articles linking methyl methacrylate and occupational asthma and that it is not clear that the FDA ever considered such a risk. Howmedica responds that the FDA decided on the wording of the warnings for the Simplex package insert with full awareness of the respiratory risks.

IV.

A grant of summary judgment is reviewed de novo. *United States* v. *Scherping*, 187 F.3d 796, 800 (8th Cir. 1999). Summary judgment is proper when there is no genuine issue of material fact and the moving party would be entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322-23 (1986). Brooks contends that her state claim for failure to warn is not preempted under the MDA, and she also advances an argument that she has a state claim of inadequate labeling which "parallels" federal labeling requirements. Howmedica responds that the district court correctly dismissed the claims on summary judgment.

A.

State law which conflicts with federal law is preempted under the Supremacy Clause of the Constitution. U.S. Const., Art. VI, cl. 2. Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Cipollone* v. *Liggett*

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state nor federal requirements need to be "device-specific" in order to warrant federal preemption and that permitting claims such as the one alleged by Brooks would cause "over-warning" injurious to the FDA's regulatory goals and to the public health.

Group, Inc., 505 U.S. 504, 516 (1992).[7] At the time Carol Brooks was exposed to Simplex, the product was regulated as a Class III device under the MDA, which contains an express preemption provision, codified at 21 U.S.C. § 360k:

> (a) [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> > (1) which is different from, or in addition to, any requirements applicable under this [Act] to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k.

At first glance the preemption issue presented here under § 360k might seem quite simple since the state law result sought by Brooks relates to safety and would impose different or additional requirements on the product warning for Simplex. That the issue is not so simple is evidenced by *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470 (1996), a case in which a sharply divided Supreme Court interpreted § 360k.

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[7] Howmedica asserts that Brooks' failure to warn claim is expressly preempted by § 360k, but on appeal it has also argued in the alternative that her claim is impliedly preempted under federal law. Because we find express preemption, we do not address any potential issue of implied preemption. We notice parenthetically, however, that the Supreme Court recently held that state law claims of fraud on the FDA are impliedly preempted under federal law, "express[ing] no view" on whether such claims are subject to express preemption under § 360k. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 348 n.2 (2001).

Lohr involved claims relating to the design, manufacture, and labeling of a pacemaker, including claims for common law failure to warn and violation of FDA regulations. *Id.* at 481, 495. The manufacturer unsuccessfully attempted to persuade a majority of the Court that Lohr's failure to warn claim was barred by the MDA preemption provision. The Court split, with Justice Breyer the swing vote as he joined first one group of justices, then the other. Justice Stevens, writing for a four justice plurality, stated that § 360k would rarely, if ever, preempt state common law claims. *Id.* at 502. Justice O'Connor on behalf of four dissenting justices disagreed, believing that § 360k preempts any state requirement — including a common law duty — that is "different from, or in addition to" a federal requirement. *Id.* at 514. Justice Breyer agreed with Justice O'Connor that state common law claims can be subject to preemption under § 360k, *id.* at 503, but he joined Justice Stevens and the plurality in ruling on *Lohr's* claim for failure to warn.

In a part of the opinion written by Justice Stevens and joined by Justice Breyer, the *Lohr* Court examined the regulations promulgated by the FDA which contain the agency's interpretation of § 360k:

> (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements * * *.
>
> (1) [§ 360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices * * * or to unfair trade

> practices in which the requirements are not limited to devices.
>
> * * *
>
> (6)(ii) Generally, [§ 360k] does not preempt a State or local requirement prohibiting the manufacture of * * * misbranded devices [unless] such a prohibition has the effect of establishing a substantive requirement for a specific device, *e.g.*, a specific labeling requirement, [that is] different from, or in addition to, a Federal requirement established under the act * * *.

21 C.F.R. § 808.1(d) (2000). These regulations attempt to clarify the intended meaning of the statutory language, and the *Lohr* Court said it was "substantially informed" by them. 518 U.S. at 495.

Drawing on the statute and the regulations, the Stevens majority in *Lohr* described a series of requirements necessary for a finding of preemption under the MDA. State requirements are preempted only if they relate to "the safety or effectiveness of the device" or to another matter included in a requirement applicable to the device. *Id.* at 500. State requirements must be "with respect to" medical devices, and state requirements of "general applicability" are subject to preemption only if they have the effect of establishing a substantive requirement for a specific device. *Id.* Federal requirements must also be "applicable to the device" at issue; that is, they must be "specific counterpart regulations" or specific to the particular device. *Id.* State law will be preempted under the MDA when "a particular state requirement threatens to interfere with a specific federal interest." *Id.*

The Court concluded that Lohr's failure to warn claim was too general to require preemption. *Id.* at 502. Although the duty to inform users of potential product dangers applies to all manufacturers, this general duty was "not specifically

developed 'with respect to' medical devices." *Id.* at 501. Medtronic's duty to warn in respect to the pacemaker was not the kind of "requirement[ ] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.*

If some of the language in *Lohr* were read without careful consideration of the separate opinions, it might imply that no state tort claim could ever be preempted since each is based on broadly applicable common law duties. Such a reading would directly contradict the view of a separate majority of the Court, however, for five justices concurred in Justice O'Connor's statement that § 360k "clearly preempts any state common-law action that would impose a requirement different from, or in addition to" a specific federal requirement. *Id.* at 511. See also *id.* at 503 (Breyer, J., concurring).

The crux of the disagreement in *Lohr* between the Stevens majority and the dissenters is the meaning to be given to the statutory phrase "a requirement different from, or in addition to." *Lohr* instructs that state requirements — including common law duties — are preempted to the extent that they interfere with specific federal requirements. The state and federal restrictions must be "carefully compar[ed]" to ascertain whether there is interference between them — that being the "overarching concern" of the test articulated by Justice Stevens and joined in by Justice Breyer. *Id.* at 500. A state claim will be preempted in circumstances where "a particular state requirement threatens to interfere with a specific federal interest." *Id.* In his concurring opinion Justice Breyer phrased the issue as whether an "actual conflict" exists between the state and federal requirements, *id.* at 508,[8] and that opinion

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[8] In his opinion Justice Breyer cited earlier Supreme Court cases describing "conflict" preemption. 518 U.S. at 507. Among the cases he cited was *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992), which explained that a state requirement is preempted if it actually conflicts with a federal requirement, either

deserves close attention since his vote created the majority. The key question before the court is whether the specific state requirement Brooks wishes to impose on Simplex would interfere with a specific federal requirement, but the question may also be phrased as whether the specific state and federal requirements conflict.

In *Lohr*, the plaintiff's failure to warn claim did not conflict with the federal requirements imposed on the Medtronic pacemaker. The product had received FDA approval through a system intended to allow rapid introduction of improvements to existing devices. *Id.* at 478. Under the § 510(k) process[9] involved in *Lohr*, a device can be sold without PMA approval if it is "substantially equivalent" to one already on the market. See 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. 814.1(c)(1) (2000). A substantially equivalent device is examined in the § 510(k) process only for similarities with existing devices; safety and effectiveness are not the focus. *Lohr*, 518 U.S. at 493. Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own. *Id.* at 493-94. The pacemaker there was subject to a federal regulation requiring Medtronic to provide a label indicating "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). This requirement applied to all manufacturers in the industry and reflected generic concerns about device regulation. It did not require the FDA to be involved in the drafting or approval of the pacemaker's product label. The requirement was not specific, and a common law claim would not "impede the ability of federal regulators to implement and enforce" it. 518 U.S. at 501.

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because compliance with both is impossible or because the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 98 (1992) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)).

[9] The type of process established under § 510(k) of the MDA as enacted in 1976.

The facts in the case before the court are very different from those in *Lohr*. The FDA drafted or approved every word of the Simplex label, and any changes were subject to close FDA scrutiny. PMA review typically requires 1,200 hours of rigorous testing for device safety. In contrast, § 510(k) review focuses on "substantial equivalence" and is completed in an average of twenty hours. *Id.* at 479. The two processes are "by no means comparable." *Lohr*, 518 U.S. at 478.

B.

Our court considered the preemptive effect of the MDA in a decision predating *Lohr*, *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). In *Martello*, we held that the PMA is a specific federal requirement within the meaning of § 360k which preempts state court claims involving safety "when the claims would impose additional requirements in areas [it has] regulated." *Id.* at 1169. Under *Lohr* this holding requires some modification because common law claims are only preempted to the extent that they threaten to interfere with specific federal requirements. 518 U.S. at 501-02.

Most courts of appeal have interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements. See, *e.g.*, *Martin* v. *Medtronic Inc.*, 254 F.3d 573, 582 (5th Cir. 2001); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 230 (6th Cir. 2000); *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). But see *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (common law failure to warn claim is not subject to preemption under the MDA). *Martin*, *Kemp*, and *Mitchell* all considered failure to warn claims involving products which had had a full PMA like that undergone by Simplex. The Fifth Circuit in *Martin* concluded that a general duty of care under state law is preempted if "the elements needed to prove [its] violation" are specific and

"therefore threaten specific federal requirements." 254 F.3d at 582. Because the design of the Martin product label had been approved by the FDA through the PMA process, a failure to warn claim would impose state requirements that would conflict with specific federal requirements and it was therefore preempted. *Id.* at 584-85. Similarly, the Sixth Circuit in *Kemp* held that a common law claim is preempted if it would add "different" or "additional" elements to specific federal requirements approved through the PMA. 231 F.3d at 236. The Seventh Circuit also concluded in *Mitchell* that when a manufacturer has adhered to the PMA process, a common law claim of mislabeling is preempted because it would impose "different" or "additional" requirements. 126 F.3d at 913-14. *Cf. Papike*, 107 F.3d at 742 (failure to warn claim preempted by FDA labeling regulations regarding toxic shock syndrome).

Those circuit court decisions since *Lohr* which have not found preemption in failure to warn cases were faced with circumstances different from those in this case. In *Oja*, the Tenth Circuit held that a common law duty to warn is not a "substantive requirement" subject to preemption, but that case involved approval through an investigational device exemption, a considerably less rigorous process than the full PMA. 111 F.3d at 786-87, 789. In *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), a case in which the FDA had issued no statement or order of requirements beyond review and approval of the initial PMA, the Eleventh Circuit ruled that simple approval of the PMA application imposes no federal "requirements." *Id.* at 1375. The *Goodlin* court implied, however, that it would find preemption in a case involving an "ascertainable requirement in an express FDA" order or regulation. *Id.* (citing *Papike*, 107 F.3d at 740-41). That is what we have here, where the FDA has issued a series of specific mandates regarding the label for Simplex. Simplex has been subject to continuing and specific

FDA regulation, beyond its initial approval through the PMA process.

C.

The failure to warn claim asserted by Brooks would interfere or conflict with the specific federal requirements imposed during the regulation of Simplex. A jury finding of negligent failure to warn would be premised on the fact that the label for Simplex was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements. Justice Breyer illustrated this principle in his concurring opinion in *Lohr* when he pointed out that if a jury were to find negligence in the use of a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation. *Id.* at 504 (Breyer, J., concurring).[10]

The effect of a jury finding of negligent failure to warn would be that state law would require Howmedica to change the label and package insert for Simplex, but Howmedica may not unilaterally make such changes under federal law. A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. 21 C.F.R. § 814.80 (2000). A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. *Id.* at § 814.39(a). Brooks points out that the regulations permit manufacturers to make temporary changes in the in-

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[10] See also *Martin*, 254 F.3d at 582-83; *Kemp*, 231 F.3d at 237 (Moore, J., concurring). Also illustrative is the report of one of Brooks' experts (Frank Junghans), which proposed revisions to the label, safety sheet, and package insert for Simplex, including additional language and colorful pictographs. A jury might adopt any of his suggestions as a state requirement after a trial on a common law claim.

terest of safety, see *id.* at § 814.39(d), but such changes are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application. *Id.* at § 814.39(a)(2), (d)(1). Once the Supplemental PMA has been approved, modified, or denied, the manufacturer must comply with the FDA's decision. *Id.* at § 814.80.

Brooks argues that limiting the warnings on a label would not seem to advance the FDA's purpose to ensure device safety. There are, however, a number of sound reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users. Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design. See generally Ctr. for Devices & Radiological Health, U.S. Dep't of Health & Human Servs., *Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers* 42 (2001), available at <www.fda.gov/cdrh/ohip/guidance/1128.pdf>. See also Richard M. Cooper, Drug Labeling and Products Liability: *The Role of the Food & Drug Administration*, 41 FOOD, DRUG & COSM. L.J. 233, 237-38 (1986). The FDA's enabling statute also reflects these concerns: warnings must be "prominent[ ]" and "conspicuous[ ]," as compared with other material on the label. 21 U.S.C. § 352(c).

The arguments advanced by Brooks ignore the need for national uniformity in product regulation, one of the explicit goals of the MDA. The legislative history indicates that this was the reason the preemption provision was included within the MDA. H.R. REP. NO. 853, 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened."). The state requirement in this case would come from a com-

mon law duty as applied by an individual jury. Trials of tort claims pose incentives to overwarn: "the visible monetary costs of additional warnings are typically quite low — a few pennies for a bit more paper and a little more ink." James A. Henderson & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 297 (1990). It would be difficult for a jury focused on a single case to take into account "the cumulative, systemic effects" of a series of verdicts. Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2175 (2000). In contrast, the FDA possesses a broader perspective. Regulation by the FDA allows the agency to craft labels that maximize safety and effectiveness.

Brooks also claims that an alleged link between methyl methacrylate and occupational asthma first became known in 1985, well after the original FDA approval of Simplex in 1971. She suggests that the FDA did not consider such a danger nor impose any warning requirement with respect to it. She bases this argument on the fact that two articles appeared in 1985 which describe case studies linking methyl methacrylate and occupational asthma and one claimed there had been no previous published report of the chemical's association with asthma. S. Lozewicz et al., *Occupational asthma due to methyl methacrylate and cyanoacrylates*, 40 THORAX 836, 836 (1985). Neither of the two experts put forward by Brooks nor the cited articles claimed, however, that the risk of respiratory irritation from methyl methacrylate had not been previously appreciated, and the product labeling for Simplex and the "Dear Doctor" letter are evidence to the contrary.[11]

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[11] There is evidence that even by 1998 a specific connection between methyl methacrylate and occupational asthma had not been conclusively established. See World Health Organization, et al., Concise International Chemical Assessment Document No. 4,

The record demonstrates that the FDA was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and the agency required Howmedica to take specific steps in response. The label for Simplex incorporated the danger of sensitivity to vapors from the very beginning. When Simplex was introduced in 1971, the FDA drafted a package insert which warned that the liquid methyl methacrylate used in mixing is "highly volatile" and that the mixing process required both "adequate air circulation" and caution "to prevent excessive exposure to the concentrated vapors" which could produce "irritation of the respiratory tract." In 1973 Howmedica requested permission to add to the warning to indicate that the ingredients of the product could "act as a sensitizer," but the FDA decided on different wording, requiring a warning about "strict adherence to the mixing instructions" to "diminish the possibility of hypersensitivity reactions" and to prevent absorption of the product.

The FDA conducted an official review of the inhalation toxicity of methyl methacrylate vapors by operating room personnel in 1975, and it subsequently directed Howmedica to send a "Dear Doctor" letter to Simplex users drafted by both Howmedica and the FDA. The letter directed user attention to methyl methacrylate vapor inhalation studies and to the package insert warning and recommended that user facilities be inspected for adequate ventilation. The FDA also mandated changes in the package label. The new version read:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum

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Methyl Methacrylate 5 (1998) ("Although occupational asthma associated with methyl methacrylate has * * * been reported, there is no conclusive evidence that methyl methacrylate is a respiratory sensitizer.")

> amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver. (emphasis added)

In 1986, after receiving reports of damage to soft contact lenses, Howmedica requested, and the FDA approved, an additional warning for the Simplex package insert referring to the vapors created during the mixing process as "noxious and irritating."

The FDA was deeply involved in drafting and editing the warnings on the Simplex label and package label, beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it. Through its approval of the PMA application for Simplex and its continuing series of directives, the agency imposed specific federal requirements on Howmedica. The failure to warn claim Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these "particular state requirement[s] threaten[ ] to interfere with * * * specific federal interest[s]," *Lohr*, 518 U.S. at 500, Brooks' claim is preempted by the MDA.

D.

Brooks also argued in the district court that Simplex instructions were inadequate under federal law because FDA regulations require package labeling for prescription products to contain information about "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). Brocks claims that her common law claim contains requirements identical to those imposed under federal law and is therefore not preempted. Brooks is correct in her assertion that a claim of failure to comply with FDA regulations is not preempted by the MDA, *Lohr*, 518 U.S. at

495, since such a state claim imposes no requirement "different from, or in addition to" any federal requirement. *Id.* at 496-97. See also *id.* at 513 (O'Connor, J ., concurring in part and dissenting in part). Her assertion that she has put forward such a cause of action is a separate issue, however. The district court dismissed "any claim that Howmedica failed to comply with FDA rules or regulations" because it found no showing of noncompliance. The panel treated this claim as one for negligence per se unsupported in the record. Brooks asserts that her argument has been misunderstood and that she alleges a violation of state law that "parallels" similar requirements under federal law.

This unpled claim lacks both clarity and support, and we find no error in its dismissal. To the extent that Brooks attempts to distance herself from the categorization of this claim as one for negligence per se, the claim begins to sound very similar to the preempted failure to warn claim just discussed. *Cf. Papike*, 107 F.3d at 742-43 (denying a claim that general labeling regulations require warnings beyond those contained in specific FDA requirements). Under the type of theory Brooks advances the general duty of C.F.R. 801.109(c) could trump even the most specific FDA labeling directive and § 360k of the MDA could be completely circumvented. Moreover, Brooks has presented no evidence that Howmedica violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels failed to meet regular reporting requirements, failed to report a known hazard to the FDA, or failed to comply with federal law in any other respect. We conclude that this claim was properly dismissed on summary judgment.

V.

Simplex package labeling was subject to meticulous and ongoing federal regulation from the product's approval in 1971 through the time of Brooks' exposure to it. The FDA imposed specific federal requirements on Simplex through

the PMA and NDA process. The specific state requirement Brooks seeks to establish by her common law claim would interfere with the specific federal requirements set for Simplex. Her claim is therefore preempted under § 360k of the MDA because it would impose a specific state requirement "different from, or in addition to" specific federal requirements. There is also no showing that Howmedica violated federal regulations. For these reasons, we affirm the judgment of the district court.

BYE, Circuit Judge, with whom HEANEY, Circuit Judge, joins, dissenting in part.

The majority stitches together a coherent, scholarly explication of § 360k preemption from the complicated opinions of the Supreme Court in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 495 (1996). I admire the majority's efforts. I also agree with its development of a three-step test, in which courts must discern the federal requirement imposed on a medical device manufacturer, then the state requirement imposed on that manufacturer, and finally compare the two to determine whether they present conflicting obligations. Though I agree with the standard expressed by the majority, I strongly disagree with its application of that standard to the facts of Carol Brooks's case and I respectfully dissent in that respect.

Following *Lohr*, we search for incompatibility between state laws (or putative state court judgments) and federal requirements imposed on manufacturers. Howmedica claims that the FDA's labeling requirements for Simplex conflict with a hypothetical adverse judgment on Brooks's state-law failure-to-warn claim. Howmedica raises two distinct arguments in support of this claim, but neither survives careful scrutiny. The majority adds two considerations in favor of

preemption that I find unpersuasive. I address these four arguments in turn.

I

Howmedica professes that it is powerless to alter Simplex's packaging or warning insert, and hence it could not comply both with a state-law judgment and the federal labeling regulations. In effect, while a state-law judgment would require Howmedica to add to its labeling and package insert, it asserts, federal regulations would require Howmedica not to add to its labeling and package insert. Howmedica submits that this Catch-22 epitomizes the need for, and importance of, § 360k preemption.

Howmedica's argument misstates a critical premise. FDA labeling regulations do not mandate that Simplex's label and package insert remain freeze-framed in their 1971-approved state. The FDA's regulations authorize Howmedica to initiate changes to Simplex's labeling. See 21 C.F.R. §§ 814.39(d)(2)(i) (authorizing medical device manufacturers to change labels to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"), (d)(2)(ii) (permitting "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device"). Section 814.39(d)(2) is not a moth-eaten relic of past regulatory efforts to which we attach little or no importance. The provision is a vital component of the FDA's larger regulatory mission of ensuring that manufacturers amend their warnings and their products in response to safety concerns and scientific advancements. The Supreme Court explicitly acknowledged the provision's importance in *Lohr*: "We also note that the agency permits manufacturers of devices that have received PMA to make certain labeling * * * changes which would enhance the safety of the device or the safety in the use of the device without prior FDA approval. See 21 CFR §§ 814.39(d)(1) and (2) (1995)." *Lohr*, 518 U.S. at 497 n. 16 (punctuation removed).

If, for example, Howmedica learns that Simplex poses an unforeseen risk to consumers' health, Howmedica may immediately alter Simplex's labeling and package inserts to warn users of the newly-discovered risk. Howmedica does not have the final say, of course; Howmedica has only the power to initiate review before the FDA concerning the merits of additional warnings. Interim warnings added by a manufacturer must be simultaneously submitted for FDA approval, and the proposed additions will be vetted by FDA doctors. If the FDA approves the additional warnings, the manufacturer may continue to display them. If the FDA rejects the additional warnings, however, the manufacturer must then remove the warnings to maintain compliance with the FDA's specific mandate. In sum, while FDA approval is pending, a manufacturer may include additional warnings on labeling and package inserts.

Section 814.39(d)(2) relieves any tension between Brooks's failure-to-warn claim and the FDA's ongoing oversight of Simplex labeling. Simplex's label and package insert have never contained warnings or information about the risk of contracting asthma. Brooks asserts that the scientific community began to learn of the asthma-inducing propensity of methyl methacrylate vapors in 1985 and 1986, more than a decade after the FDA approved Simplex for use in the United States. Brooks claims that Howmedica negligently failed to warn Simplex users that repeated exposure to vapors released in the mixing process could cause occupational asthma. Though the FDA approved Simplex's labeling without the type of asthma warnings suggested by Brooks, Howmedica could have sought FDA approval to add such warnings in the mid-1980s. Under § 814.39(d)(2), Howmedica could have altered its label or package insert — unilaterally — to alert users to the dangers of contracting asthma, pending permanent FDA approval of those warnings.

Had the FDA refused permission to add asthma warnings, Brooks's failure-to-warn claim would almost certainly be

preempted. In that hypothetical instance, Howmedica would face the dilemma it so fears: a state law judgment would effectively require it to add an asthma warning thatthe FDA mandated must not be included. That hypothetical example is not the present case, however. In this case, Howmedica made no effort to warn Simplex users about asthma, though it had the power to do so initially, and could have done so permanently with the FDA's approval. Brooks's attempt to hold Howmedica liable for this alleged shortcoming in no way conflicts with FDA oversight of medical device labeling generally, or with Simplex's federal labeling requirements specifically.

My understanding of § 814.39(d)(2)'s role in the preemption analysis is identical to that of the former Chief Counsel of the FDA, Richard Cooper. "In some situations, FDA has not, at the relevant time, considered the precise question of whether the insert it had previously approved should be changed in light of subsequent information. Where that is the case, there would seem to be no relevant federal decision entitled to supremacy." Richard Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 234-35 (1986) (discussing the regulatory predecessor to § 814.39(d)(2)). Cooper cautions courts not to "over-read" FDA regulations as permitting drug manufacturers carte blanche authority to change labeling or package inserts, *id.* at 235-36, a point with which I fully agree. But Cooper ultimately ascribes to the fundamental point we raise above: manufacturers possess the authority, consistent with § 814.39(d)(2), to initiate the process of changing a medical device label to warn users of a newly-discovered risk. Manufacturers who negligently fail to seek FDA approval for such additional warnings (and to supplement their warnings pending FDA approval) cannot benefit from § 360k's preemption defense because they encounter no conflict between their respective state and federal obligations.

In the present case, Brooks's state law failure-to-warn claim and the FDA's scheme of regulatory oversight may coexist without impediment, and thus preemption is inappropriate.

II

Howmedica also argues there is actual conflict between state and federal requirements — even accepting my interpretation of § 814.39(d)(2) for argument's sake. Howmedica contends the FDA rejected the type of asthma warning that Brooks advocates when it approved Simplex's initial warnings in 1971, and when it oversaw Simplex labeling changes in 1975 and 1976. Howmedica asserts it presented possible warnings to the FDA that encompassed asthma-type risks. The FDA incorporated some of those warnings into the package insert, but rejected others. In either event, Howmedica posits, the FDA's decision to accept or reject such warnings constitutes specific federal regulations inconsistent with Brooks's effort to obtain a state-law judgment requiring an asthma warning.

The record does not substantiate Howmedica's assertions. In the first place, Howmedica has not directed the court to any evidence that warnings specifically pertaining to asthma were discussed by the FDA or presented for its consideration. Howmedica is therefore left to contend that the warnings it did propose, and those considered by the FDA, encompass the same territory as an asthma warning. Howmedica argues, in effect, that some of the warnings it proposed would have "done the work" of an asthma warning, and thus the FDA's rejection of those warnings implies a specific federal prohibition. This contention also lacks any basis for support in the record presented to the district court.

The package insert warnings drafted by the FDA in 1971 during the PMA process mention the following:

> Caution should be exercised during the mixing of [Simplex's] two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

Brooks App. 202 (Aff. of Christopher Lawler, Exh. K) (Dec. 15, 1998).

It is obvious this warning does not encompass asthma in the manner Howmedica suggests. Warning a Simplex user of possible "irritation of the respiratory tract" is not equivalent to warning the user about contracting asthma through repeated exposure. The warning does not adequately reflect the medical reality of an asthmatic condition. Asthma is a chronic disease that derives from repeated exposure to irritants or allergens, see 1 Gale Encyclopedia of Medicine 347 (1999); Brooks App. 409 (Depo. of Dr. Kaye) (Dec. 16, 1998), yet the Simplex warning bears no mention of duration or long-term exposure. To the contrary, the warning implies to the reader that possible irritation will be only temporary. Moreover, the label does not even hint that such exposure might cause disease.

Howmedica's argument fares no better if the warning in fact connotes permanent harm. Viewed most charitably to Howmedica, the warning's reference to "irritation of the respiratory tract" might incorporate the possibility of long-term suffering. Brooks strongly disagrees any such inference may be drawn, and thus a dispute of material fact (perhaps a dispute of medical fact) would prevent the entry of summary judgment. Because we are presently reviewing the propriety of summary judgment entered against Brooks, we are in no position to draw factual inferences in favor of Howmedica. If such a factual dispute exists, its resolution — and thus the overarching preemption question presented in this case — would require some initial fact-finding. *Cf. Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union*, 468 U.S. 491,

511 (1984) (expressing an inability to resolve a preemption question until appropriate findings of fact had been made to permit review of the legal question).

Howmedica's assertion that the FDA considered and rejected warnings encompassing asthma in 1975 and 1976 is even less believable. In early 1975, the FDA commenced review of the inhalation toxicity of methyl methacrylate vapors. Howmedica and other manufacturers were required to participate in committee meetings and other proceedings with the FDA. As a result of these discussions, the FDA required Howmedica to alter the Simplex package insert to state Simplex's liquid component was highly flammable and operating rooms should be adequately ventilated. See Brooks App. 126 (Lawler Aff. § 40). The FDA also required Howmedica to send a "Dear Doctor" letter pertaining to concerns of inhalation toxicity. See *id.* at 325-26 (Lawler Aff., Exh. Z).

It cannot fairly be contended that the warnings the FDA required in the mid-1970s were germane to asthma. The FDA was then concerned with the inhalation toxicity of methyl methacrylate vapors. Toxins are essentially poisons. See *supra*, Gale Encyclopedia at 2878. But Brooks does not claim she was poisoned by exposure to Simplex. She claims she contracted asthma from repeated exposure to the vaporous byproducts of the Simplex mixing process. Howmedica has not directed our attention to any evidence that suggests the FDA considered and rejected warnings that would have notified Simplex users of the risk of contracting asthma. The FDA's consideration of inhalation toxicity studies simply does not indicate the FDA considered warnings related to asthma.

And even if the FDA had considered and rejected asthma warnings in the 1970s, Howmedica's counter-argument would still fail. Brooks's failure-to-warn claim is predicated upon scientific discoveries of the mid-1980s. See, *e.g.*, Brooks App. 78 (Plaintiff's Memo. Opp. Summ. J. 21) (Jan.

8, 1998) ("In 1985, scientific literature established a causal relationship between the induction of occupational asthma and exposure to methyl methacrylate, a component of Defendants' bone cement."); *id.* at 465 n. 4 (Expert report of Environmental Health & Safety, Inc.) (July 15, 1998) (citing S. Lozewicz et al., *Occupational Asthma Due to Methyl Methacrylate and Cyanoacrylates*, 40 THORAX 836 (1985)); *id.* at 480. FDA regulations require manufacturers to apprize themselves and the agency of new product risks that come to light subsequent to market approval. Howmedica could have sought FDA approval (under § 814.39(d)(2)) to add asthma warnings when scientists began to notice (or at least thought they began to notice) a causal link between methyl methacrylate vapor exposure and occupational asthma in the mid-1980s. Howmedica could have added such warnings to its package insert immediately, pending final FDA approval or rejection. Howmedica's reference to FDA actions in the 1970s is not responsive to Brooks's assertion that Howmedica failed to warn Simplex users of the risk of contracting asthma when such risks became known in 1985.

Howmedica's argument therefore fails. No evidence in the record demonstrates that current Simplex labeling warns users of the possibility of contracting asthma. Nor does any evidence suggest the FDA considered and rejected other warnings that might have encompassed asthma within their scope. The FDA has not issued Howmedica any specific federal directive pertinent to asthma, and consequently, Howmedica's claim of preemption based upon conflicting state and federal requirements melts away. The majority therefore errs in holding that Brooks's failure-to-warn claim is preempted by federal law.

III

In places, the majority seems to suggest that even if Howmedica's state and federal requirements do not conflict, Brooks's hypothetical state-law judgment nevertheless

"threatens to interfere with a specific federal interest," *ante* at 14 (quoting *Lohr*, 518 U.S. at 500), and thus her state-law claim should be preempted. See *ante* at 19 ("Such 'threaten[ed] interfere[nce]' between specific requirements of state and federal law requires preemption under the MDA.") (quoting *Lohr*, 518 U.S. at 500). I find this suggestion contrary to Lohr and legally untenable in any event.

While predicting that § 360k and its concomitant regulations will occasionally preempt state tort claims, Lohr states "it is impossible to ignore [the regime's] overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. After uttering this broad platitude, the Court got down to the business of deciding when a specific federal interest might be threatened. The ensuing paragraph considers the sort of state and federal requirements imposed on medical device manufacturers. And then, to sum up, the Court concludes "[t]he statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.*

The Court's language, and the structure of its discussion, emphasize that while the overarching concern of § 360k preemption is to prevent "threatened interference" with "federal interests," the standard by which to determine such a threat is actual conflict between state and federal requirements. In this case, there is no actual conflict between Howmedica's federal labeling requirements and the requirements imposed by a hypothetical state-law judgment for Brooks — as I have demonstrated above. It would be odd, to say the least, to discard the Court's analytical framework of conflict-motivated preemption in favor of the generic concern present in any preemption case that federal interests persevere.

It is critical to distinguish between the threat to federal interests, to which *Lohr* alludes, and the threat to a particular manufacturer, which *Lohr* does not similarly discuss. The federal interest in MDA cases will rarely if ever be threatened. The FDA always has the last word in labeling decisions. If a manufacturer presents a § 841.39 request to the FDA to add a warning, the FDA's ruling on that request will have preemptive effect. If the FDA refuses permission to add the warning, a subsequent state-law tort claim based on the failure to include that warning will be preempted. The federal interest — the FDA's regulatory mission — is never compromised by a competing state-law judgment because the FDA's decision supplants state tort law.

I acknowledge that manufacturers who are sued in tort before they request additional warnings from the FDA may be threatened. But the federal interest — the subject of discussion in *Lohr* — will not be threatened. Suppose a plaintiff prevails on a state-law failure-to-warn claim against a medical device manufacturer. After judgment is entered, the manufacturer seeks FDA approval to add the warning compelled by the state-law judgment. If the FDA refuses to approve that warning, the manufacturer need not place the warning on its labels because the FDA's requirement preempts the effect of the state-law judgment. In this scenario, the manufacturer may have lost considerable time and money defending the suit, and thus its interests have in some sense been threatened. But the federal interest has not been threatened. When the FDA was presented with a label modification request, the FDA rejected it, and the FDA's judgment carries the day and supplants the state-law judgment for the future based upon § 360k preemption. Section 360k preemption, as envisioned by the Supreme Court, could hardly protect the federal interest more capably.

I therefore resist the majority's apparent attempt to resolve this case based on generic concerns that federal interests might be "threatened."

IV

Finally, spurred on by amicus curiae, the majority makes passing reference to certain policy considerations that militate against a preemption holding in this case. The majority argues that Brooks's effort to add another warning to Simplex's label could result in "over-warning" consumers. The majority also posits that Brooks's lawsuit should not establish medical device labeling policy because she lacks the FDA's capacity to appreciate and balance all the risks presented.

These arguments suggest the FDA's regulations and directives should always supplant state tort suits. Yet the Supreme Court implicitly rejected these policy arguments in *Lohr* by holding at least one plaintiff's state-law failure-to-warn claim was not preempted under § 360k.

Moreover, the majority's considerations form an inappropriate basis for resolving an express preemption case. When Congress has declared its preemptive intent in statutory form, we are limited to interpreting its language in discerning the scope of federal preemption. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (declaring that the preemptive scope of the Federal Cigarette Labeling and Advertising Act is "governed entirely" by the language in its express preemption provision, 15 U.S.C. § 1334(b)). In the MDA, Congress set forth its intention to preempt some state regulations and requirements placed on medical device manufacturers. Reasonable jurists may debate the meaning of § 360k's words as they apply to particular cases. But we may not rely on broader considerations of public policy, for then we overstep our duty faithfully to interpret the language upon which Congress has agreed.

I respectfully dissent in part, though I do join in Part IV.D of the majority opinion, which concludes that the district court properly granted summary judgment as to Brooks's seeming negligence per se claim.

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No. 01-441

IN THE

Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITIONERS' SUPPLEMENTAL BRIEF IN RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

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PETITIONERS' SUPPLEMENTAL BRIEF IN RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

Respondent has filed a supplemental brief directing the Court's attention to the Eighth Circuit's recent en banc decision in *Brooks v. Howmedica, Inc.*, ___ F.3d ___, 2001 WL 1568430 (Dec. 11, 2001). *Brooks* held that a state-law failure-to-warn claim concerning a device that had undergone FDA pre-market approval ("PMA") was preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. Respondent explains, at some length, why it believes that *Brooks* is correctly decided, a point that is irrelevant if, as is the case here, there remains a significant split in appellate authority on the question presented that will persist without this Court's intervention.

As to the merits in *Brooks*, only two points are noteworthy. First, *Brooks* presented only the narrow question whether a failure-to-warn claim is preempted by the MDA in light of the approval process for the device at issue in that case. It did not address all failure-to-warn claims and it did not consider other types of damages claims, such as those alleging design defect, manufacturing defect, and violation of a state consumer protection statute, which are presented here and in many of the other decisions that have divided the federal and state courts. Second, the holding in *Brooks*, limited as it is, is flatly at odds with 21 C.F.R. 814.39(d)(2). That provision "relieves any tension between Brooks's failure-to-warn claim and the FDA's ongoing oversight of [the product's] labeling," Resp. Supp. Br., App. 27a (Bye, J., joined by Heaney, J., dissenting), because it explicitly allows manufacturers to add new label warnings and contraindications to enhance consumer safety without prior FDA approval. *See also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497 n.16 (1996) (relying on 21 C.F.R. 814.39(d)(2)).

Respondent also uses *Brooks* to attempt to distinguish two of the principal no-preemption decisions at the heart of the split in appellate authority. First, respondent asserts that *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), can be ignored because the device there was marketed under a different approval process from the one at issue here. But that point is irrelevant in light of *Oja*'s rationale. *Oja* found that the FDA had mandated at least one warning that constituted a specific federal "requirement" within the meaning of 21 U.S.C. 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was premised on "a general [state-law] duty ... 'to inform users and purchasers of potentially dangerous items of the risks involved in their use.'" *Id.* at 789 (quoting *Lohr*, 470 U.S. at 501). Indeed, despite respondent's claim to the contrary, the Eighth Circuit characterized *Oja*'s holding in the same manner as do petitioners. *See* Resp. Supp. Br., App. 17a, 18a. That holding is correct under *Lohr*. More important for present purposes, if that holding were applied here petitioners' general state-law claims would not be preempted. Put differently, *Oja* is irreconcilable with the decision below.

Second, respondent also attempts to distinguish *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which, in direct contrast to the decision below, held that PMA approval does not trigger preemption of state-law damages claims. Despite that holding, respondent suggests that, under *Goodlin*'s rationale, preemption might occur where the agency approval contains an "'ascertainable requirement in an express FDA' order or regulation." Resp. Supp. Br. at 2 (quoting *Brooks*, in turn quoting *Goodlin*). However, PMA approvals are not issued as device-specific agency orders or regulations, but rather under highly general FDA form letters applicable to all PMA devices. *See Goodlin*, 167 F.3d at 1377. In any event, even if one could properly infer a narrower reach to the *Goodlin* holding such an inference would do nothing to eliminate the split in authority between *Goodlin* and the

decision of the Fifth Circuit below. As noted in the petition (at 3-4), *Goodlin* and the decision below came to opposite results *regarding the same medical device marketed under the same FDA approval letter*. It is difficult to conceive of a cleaner split in authority warranting this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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